

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA115: Naltrexone for the management of opioid dependence

This guidance was issued in January 2007
The review date for this guidance is March 2010

Recommendation

- A review of the guidance should be transferred to the 'static guidance list'. That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	The absence of significant new evidence means that this would be a poor use of NICE resources
The decision to review the guidance should be deferred [to a specified date].	We do not anticipate a date when significant new evidence will emerge.
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	No appropriate related technology appraisals (TAs) have been found.
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	The most obvious related technology, a depot formulation of naltrexone, remains unlicensed at this point, and is therefore currently not appraisable by NICE. No appropriate, newly-referred technology appraisals have been found.
A review of the guidance should be incorporated into an on-going clinical guideline.	There is no current guideline at present that could fully encompass the scope of this TA.
A review of the guidance should be updated into an on-going clinical guideline.	There is no current guideline at present that could fully encompass the scope of this TA.
A review of the guidance should be transferred to the 'static guidance list'.	Given that we do not anticipate the emergence of new evidence in the foreseeable future we recommend this option.

Original remit(s)

To appraise the clinical and cost effectiveness of naltrexone as a treatment for relapse prevention for drug misusers and to identify those groups of drug misusers (in the community and prison settings) who are most likely to benefit from being prescribed naltrexone. Also to advise on the optimum care package that needs to be available to those prescribed naltrexone to secure effective outcomes, and to provide guidance to the NHS in England and Wales.

Current guidance

- 1.1 Naltrexone is recommended as a treatment option in detoxified formerly opioid-dependent people who are highly motivated to remain in an abstinence programme.
- 1.2 Naltrexone should only be administered under adequate supervision to people who have been fully informed of the potential adverse effects of treatment. It should be given as part of a programme of supportive care.
- 1.3 The effectiveness of naltrexone in preventing opioid misuse in people being treated should be reviewed regularly. Discontinuation of naltrexone treatment should be considered if there is evidence of such misuse.

Relevant Institute work

Published

Methadone and buprenorphine for managing opioid dependence. Technology Appraisal 114. Published: January 2007. Expected review date: March 2010

Drug misuse: opioid detoxification. Clinical guideline CG52. Issued: July 2007. Expected review date: July 2010

Drug misuse: psychosocial interventions. Clinical guideline CG51. Issued: July 2007. Expected review date: July 2010

Interventions to reduce substance misuse among vulnerable young people. Public health guidance PH4. Published: March 2007. Expected review date March 2010

Needle and syringe programmes: providing people who inject drugs with injecting equipment. Public health guidance PH18 Published: February 2009. Review date: tbc.

In Progress

Psychosis in conjunction with substance misuse: the assessment and management of psychosis with substance misuse. Clinical guideline.
Expected issue date Mar 2011

In Topic Selection



Safety information

Nothing relevant found

Details of new indications

No new indications found

Details of new products

Drug (manufacturer)	Details
Naltrexone depot (Alkermes)	Phase III for opioid dependence
Oxycodone (Elite)	Phase III as add on to naltrexone in this indication
Oxycodone (Alpharma)	Phase II as add on to naltrexone in this indication
Dronabinol	Phase III as add-on to naltrexone in this indication

On-going trials

Trial name and contact	Details
Behavioral Naltrexone Therapy (BNT) for Promoting Adherence to Oral Naltrexone (BNT-oral) vs Extended Release Injectable Depot Naltrexone (Depot-BNT); a Randomized Trial. A Free Treatment for Opiate Abuse.	Phase III Estimated completion date: August 2011
Buprenorphine Maintenance vs. Detoxification in Prescription Opioid Dependence	Phase IV Currently recruiting Estimated completion date: April 2012
Addiction Treatment in Russia: Oral vs. Naltrexone Implant	Phase II/III Ongoing Estimated completion date: October 2009
Comparison of	Phase IV

Buprenorphine/Naloxone With Naltrexone in Opioid Dependent Adolescents	Currently recruiting Estimated completion date: May 2011
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New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from 2005 onwards were reviewed. The results of the literature search are discussed in the 'Appraisals comment' section below.

Implementation

A submission from Implementation is attached at the end of this paper.

Equality and diversity issues

None

Appraisals comment:

No new evidence was identified that would change the original recommendation: 'naltrexone is recommended as a treatment option in detoxified formerly opioid-dependent people who are highly motivated to remain in an abstinence programme'. As such it is recommended that this guidance be placed on the static list.

There were some new data from randomised controlled trials but it was not considered relevant for the following reasons: one trial (Schottenfeld, 2008) compared naltrexone to buprenorphine to placebo in patients receiving detoxification. Given that in TA115, naltrexone was appraised for 'detoxified formerly opioid-dependent people' in line with its licensed indication, the trial focussed on a different position in the treatment pathway than that considered within the TA115 guidance. Two other published studies (Hulse, 2009 and Kunøe, 2009) compared oral naltrexone to a naltrexone implant (naltrexone depot), exploring if the implant will reduce non compliance and therefore improve outcomes. No information was found in the literature regarding when the naltrexone implant will be licensed. NICE contacted the manufacturer in order to obtain additional information on the naltrexone implant, but received no response. Because no information is available on the efficacy and cost of the implant, it is unclear how the guidance for oral naltrexone would be affected by the naltrexone implant.

Summary

There is no new evidence relevant for this appraisal and no information available about any potential marketing authorisation for the alternative presentation (implant). We therefore suggest that this is put on the static list

and only revived if we receive information about a marketing authorisation for the implant and its cost.

GE paper sign off: Elisabeth George, 29 07 2010

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NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

IMPLEMENTATION DIRECTORATE

Guidance Executive Review

Technology appraisal 115: Drug misuse - Naltrexone

1. National Prescribing

1.1 Hospitals

Data showing trends in prescribing costs and volume are presented below. Unfortunately this data does not link to diagnosis so needs to be treated cautiously in relation to the specific recommendations of the guidance. Estimated costs are also calculated by IMS using the drug tariff and other standard price lists. Many hospitals receive discounts from suppliers and this is not reflected in the estimated cost.

Figure 1 Trend in volume of prescribing naltrexone in hospitals in England

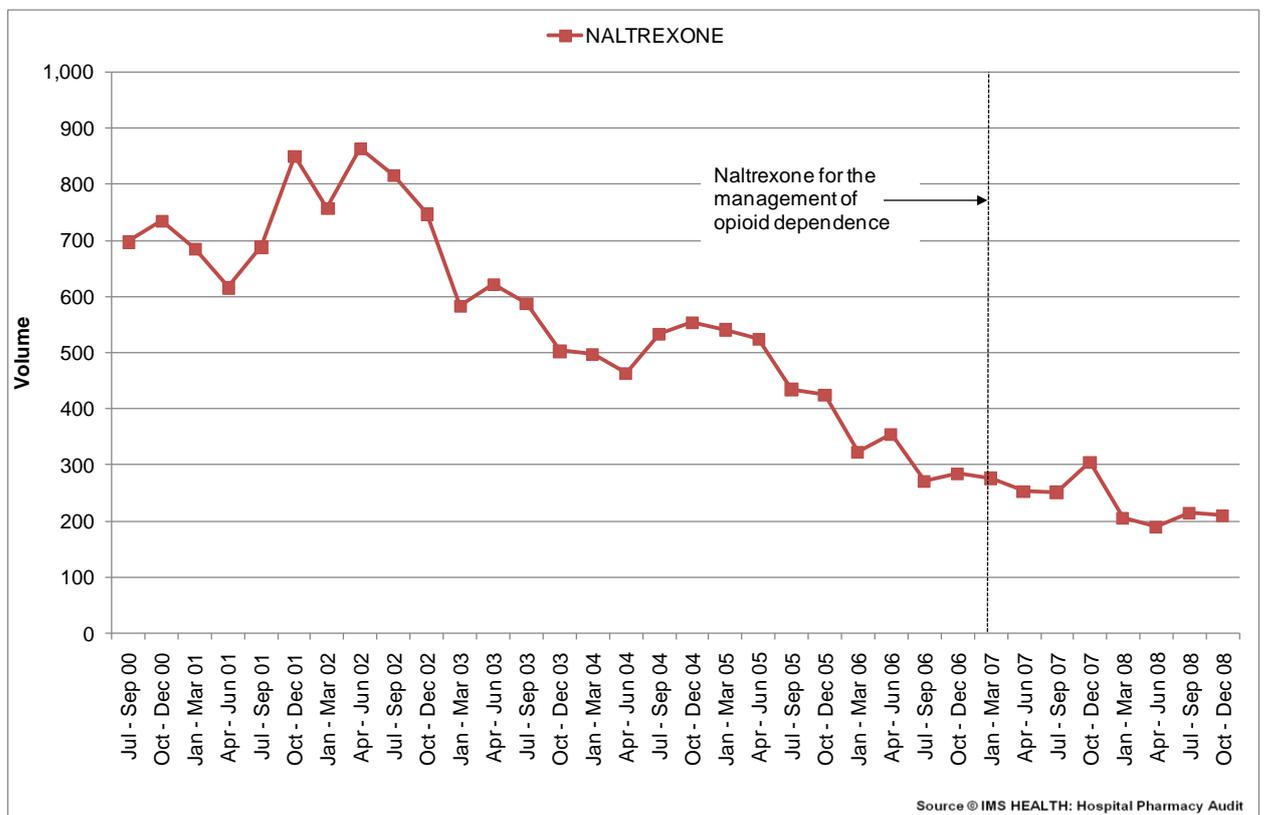
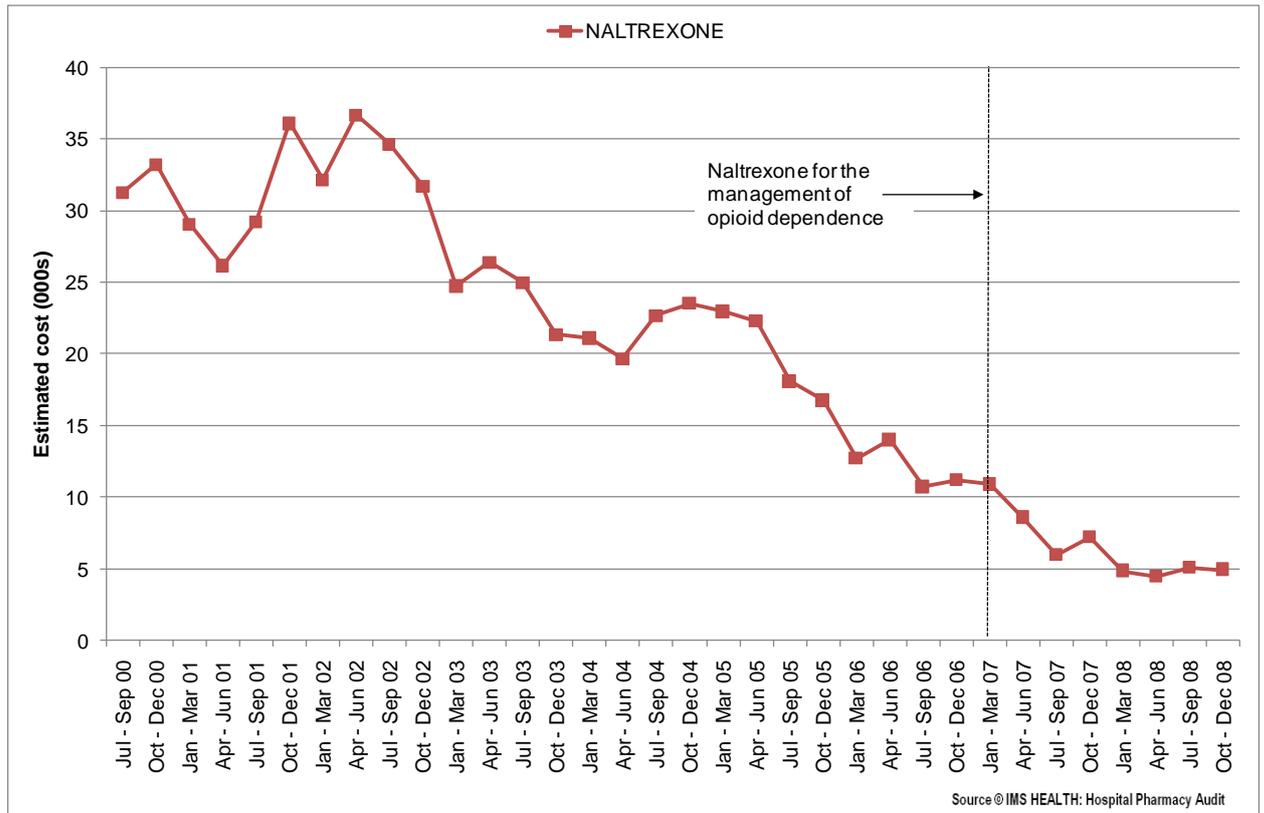


Figure 2 Trend in cost of prescribing naltrexone in hospitals in England



1.2 Primary care

This section provides information on prescribing cost and volume for naltrexone dispensed in the community in England. The data are obtained from the Prescription Cost Analysis (PCA) system, supplied by the Prescription Services Division of the NHS Business Services Authority, and is based on a full analysis of all prescriptions dispensed in the community. Also included are prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. The data do not cover drugs dispensed in hospitals, including mental health trusts, or private prescriptions. All costs stated in this report are based on net ingredient cost (NIC).

Figure 3 Items prescribed and dispensed in the community in England of naltrexone

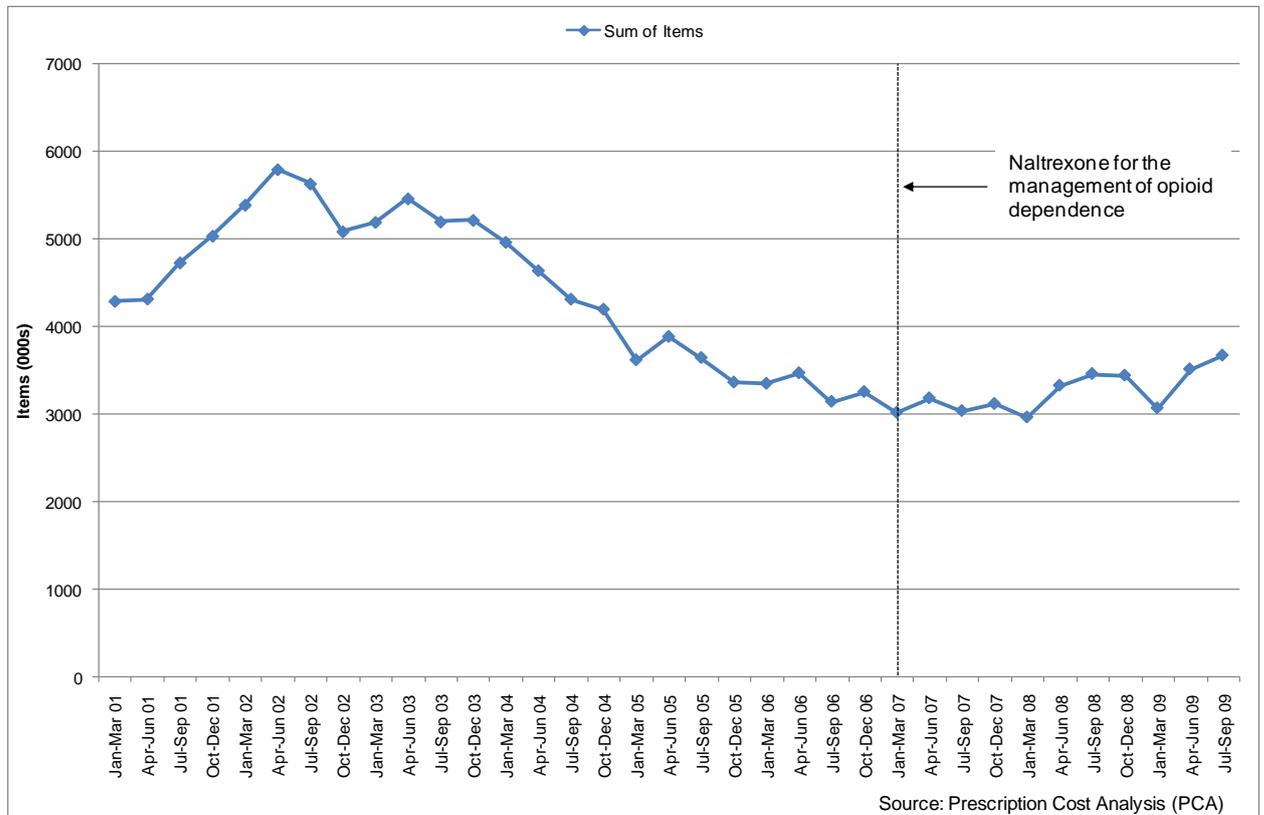
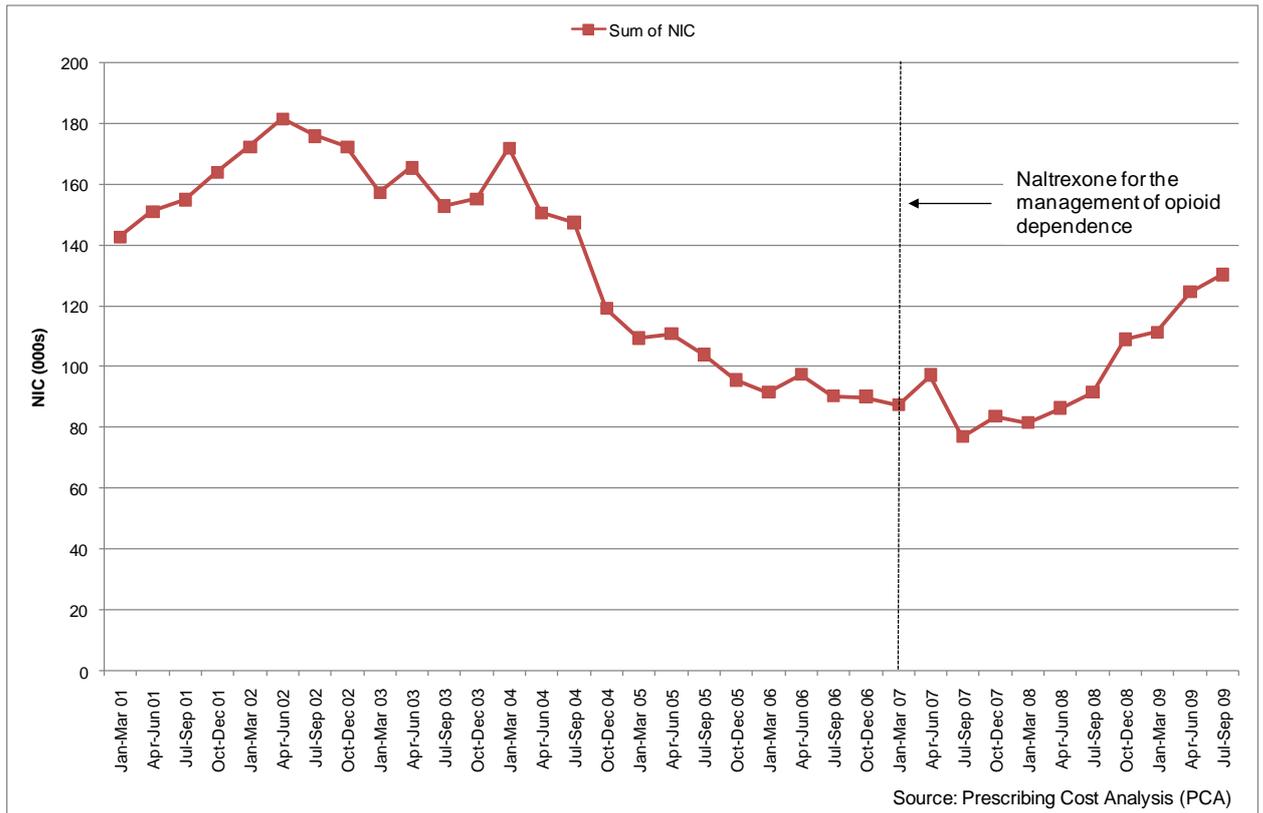


Figure 4 prescribing cost of naltrexone prescribed and dispensed in the community in England



2. External literature

2.1 ERNIE

2.1.1 The Information Centre for Health and Social Care (2009) Hospital Prescribing, 2008: England

http://www.ic.nhs.uk/webfiles/publications/Primary%20Care/Prescriptions/hospre08/Hospital_prescribing_2008_report2.pdf

Cost (£000s)	Primary care	% growth primary	FP10HP*	% growth	Hospital	% growth hospital	Total	% growth total
Naltrexone	338.8	12.5	30.0	-32.6	19.3	-40.7	388.1	2.6

*FP10HP = prescriptions written in hospitals but dispensed in the community

The data shows that the majority of prescribing for naltrexone is carried out in a primary care setting.