South West Yorkshire Area Prescribing Committee

Naltrexone Shared Care Guideline

Introduction	
General statements	• Naltrexone is used as an adjunct to psychological interventions to support those who are trying to remain abstinent. It helps to reduce the risk of relapse to heavy drinking by reducing the desire for alcohol. A large database of high quality evidence was reviewed by NICE and it was felt that in moderate to severe alcohol dependence Naltrexone is effective in reducing the rate of relapse. Naltrexone is recommended in a review of the effectiveness of treatment for alcohol problems by the NTA 2006. NICE Alcohol use disorder : Diagnosis, assessment and management of harmful drinking and alcohol dependence (NICE Clinical Practice Guideline 115 Feb 2011) recommend the use of naltrexone as first line treatment after successful withdrawal from alcohol (Recommendation 8.3.6.7). • The patient will receive supplies of the drug from the specialist community alcohol service until the transfer of shared care is agreed between consultant and primary care prescriber. • The primary care prescriber must reply in writing to the request for shared care within two weeks if unwilling to participate. • The responsibility for prescribing and monitoring must be documented clearly in the patient's specialist community alcohol service notes and general practice notes. • Shared care should only be considered when the patient's clinical condition is stable or predictable.
Indication	Naltrexone is licensed for use as an additional therapy, within a comprehensive treatment program including psychological guidance, for detoxified patients who have been alcohol dependent to support abstinence

Individual's Responsibilities	
Specialist Community Alcohol Service specialist's responsibilities	➢ To assess the suitability of the patient for treatment. ➢ To discuss the benefits and side effects of treatment with the patient/carer and the need for long term monitoring if applicable. ➢ To perform baseline tests and if appropriate routine tests until the patient is stable. ➢ It is the specialist community alcohol service responsibility to prescribe for up to the first 6 months of treatment or until patient is stable. ➢ To ask the GP whether they are willing to participate in shared care. ➢ To provide the GP with a summary of information relating to the individual patient to support the GP in undertaking shared care ➢ To advise the GP of any dosage adjustments required, monitoring required, when to refer back, and when and how to stop treatment (if appropriate). ➢ To advise the GP when the patient will next be reviewed by the specialist. ➢ To monitor the patient for adverse events and report to the GP and where appropriate MHRA (Yellow card scheme). ➢ To provide the GP with contact details in case of queries. ➢ Ensure sufficient supply of medication until GP accepts agreement to shared care

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	➢ Baseline Tests ➢ LFTs Urine drug screen for people with a history of opioid dependence ➢ Routine Tests ➢ LFTs ➢ Disease monitoring ➢ Patient should be monitored for abstinence every 6 months
Primary care prescriber's responsibilities	➢ The primary care prescriber must reply in writing to the request for shared care within two weeks if unwilling to participate. ➢ The responsibility for prescribing and monitoring must be documented clearly in the patient's specialist community alcohol service notes and general practice notes ➢ To prescribe and adjust the dose as recommended by the specialist ➢ To ensure there are no interactions with any other medications initiated in primary care. ➢ To continue monitoring as agreed with secondary care. ➢ To refer back to the specialist where appropriate. For example: • Patient or General Practitioner is not comfortable to continue with the existing regime due to either change in condition or drug side effects. • Advice in respect of concordance. • Special situations, (e.g. Pregnancy) ➢ Discontinue the drug as directed by the specialist if required. If any patients have been prescribed naltrexone beyond 6 months/ordering irregularly/not within the last 1-2 months – STOP – review and refer to specialist service if alcohol use remains a significant problem. ➢ To identify adverse events if the patient presents with any signs and liaise with the hospital specialist where necessary. To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme)
Monitoring required	Initiation should be by specialist services (Specialist Community Alcohol Service or Shared Care GP practices). Routine Monitoring LFTs and patient should be monitored for abstinence every six months.
Information given to the patient	Specialist service to discuss with the patient, and their family or carers the proposed treatment, including the possible side effects, and to obtain their agreement and commitment to proceed. Draw the patient's attention to the information card that is issued with oral naltrexone about its impact on opioid-based analgesics.
Contact details	To be included in specialist's letter

Product Information

The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics	
Dosage and administration	Relapse prevention in alcohol dependence, ADULT over 18 years [unlicensed under 18 years], 25 mg on first day, increased to 50 mg daily from day two if tolerated. 25mg dose for adjunct to prevent relapse in formerly alcohol-dependent patients is an unlicensed dose.
Adverse effects	Refer to the current BNF and www.medicines.org.uk/emc/

	Nausea, vomiting, abdominal pain, diarrhoea, constipation, reduced appetite, increased thirst, chest pain, anxiety, sleep disorders, headache, increased energy, irritability, mood swings, dizziness, chills, urinary retention, delayed ejaculation, decreased potency, joint and muscle pain, increased lacrimation, rash, increased sweating; rarely hepatic dysfunction, depression, suicidal ideation, tinnitus, speech disorders; very rarely hallucinations, tremor, idiopathic thrombocytopenia, exanthema.
Precautions and contra-indications	Refer to the current BNF and www.medicines.org.uk/emc/ Patients currently dependent on opiates (causes acute withdrawal). •Acute hepatitis. •Acute liver failure/Severe hepatic impairment (ALT>2Xnormal range). •Severe renal failure. •Hypersensitivity to Naltrexone HCl
Clinically relevant drug interactions and their management	Refer to the current BNF and www.medicines.org.uk/emc/ Opiates - the opioid dose needed to achieve the desired therapeutic effect may be larger than normal. This increases the risk of respiratory depression and circulatory effects making them more pronounced and long lasting