HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Naltrexone in Relapse Prevention (Opioid Dependence)

Patients Name:…… Unit Number: ……

Patients Address:……..

G.P's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:……

Where prescriber is not a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……..... …… Date:……

GP's Signature:…… Date:……..

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and send back to specialist, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at : http://www.hey.nhs.uk/amber.htm

SHARED CARE FRAMEWORK FOR CLINICAL INFORMATION ONLY. Drug and alcohol treatment services in Hull and East Riding are directly commissioned by Public Health with specialists and GPs, who prescribe treatment for opioid/ alcohol dependence as part of this locally commissioned Public Health service. GPs prescribing outside of these arrangements using this framework should do so in accordance with NICE guidance.

1. BACKGROUND

Naltrexone is recommended as a treatment option in detoxified formerly opioid dependent people who are highly motivated to remain in an abstinence programme. 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. 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.

These guidelines aim to provide a framework for the prescribing of naltrexone in relapse prevention by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements. This framework is supportive of NICE TA115 *Naltrexone for the Management of Opioid Dependence* January 2007

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL(91)127 “Responsibility for prescribing between hospitals and GPs”.

Naltrexone is an opioid antagonist with a high affinity for opioid receptors. It competitively displaces opioid agonists (for example, diamorphine or methadone), blocking the euphoric and other effects of opioids and thereby minimising the positive rewards associated with their use. . It is licensed as an adjunct to prevent relapse in opioid dependent individuals who are opioid free. Naltrexone should be prescribed as part of a structured aftercare plan following detoxification, to assist in relapse prevention in conjunction with other psychosocial interventions.
This framework is only applicable to GPs currently involved in methadone prescribing.

2. INDICATION COVERED BY THIS FRAMEWORK

- Highly motivated patients seeking opioid abstinence who are opioid free (i.e. abstinence from methadone for 10 day, heroin for 7 days and buprenorphine for 4 days). If it is considered appropriate by the specialist, naloxone challenge test (400-800 microgram naloxone IV) may be carried out prior to the initiation of naltrexone, to confirm the patient’s opioid status.
- Patients capable of giving informed consent and aged >18 years

3. DOSE

- 25mg following a negative naloxone challenge if appropriate
- 50mg daily thereafter
- Can be prescribed three times weekly
    - 100mg Monday
    - 100mg Wednesday
    - 150mg Friday

4. DURATION OF TREATMENT

- At least 3 months
- Optimal treatment length is variable and negotiated individually
- Liver function tests should be monitored before treatment and every 6 months during therapy, naltrexone should be discontinued if there is evidence of deteriorating liver function, hepatitis or liver failure.
-

5. ADVERSE EFFECTS

Major adverse events are rare. Side effects are common but tend to be mild, transient and improve with time. Symptoms may result from persistent mild opioid withdrawal and/or from side effects of naltrexone.

- Side effects with an incidence>10%

insomnia	asthenia	joint/muscle pain
anxiety	headache	nervousness
abdominal pain	nausea	vomiting
restlessness		

- Side effects with an incidence<10%

chills	increased energy	loss of appetite
diarrhoea	constipation	irritability
increased lacrimation	delayed ejaculation	decreased potency
increased thirst	skin rashes	increased sweating
Dizziness	feeling down or tired	Chills
tachycardia	palpitations	

- Rare but potentially serious side effects
  Liver function abnormalities (dose dependent elevation of liver enzymes)
  Idiopathic thrombocytopenic purpura

There is a risk of opioid overdose if the patient:

- **attempts to overcome the blocking effect of naltrexone**
- **stops naltrexone and resumes opioid use (due to loss of tolerance)**

6. INTERACTIONS

Concomitant administration of naltrexone with an opioid-containing medication should be avoided. Patients should be warned that attempts to overcome the blockade may result in acute opioid intoxication which may be life threatening. In an emergency requiring opioid analgesia an increased dose of opioid may be required to control pain. The patient should be closely monitored for evidence of respiratory depression or other adverse symptoms and signs.

Patients may be at risk of a fatal overdose caused by respiratory depression if they relapse while taking naltrexone. This can happen if the person tries a larger dose of diamorphine to achieve euphoria, or if they return to diamorphine use after naltrexone treatment, because of loss of tolerance to diamorphine

Insulin requirements of a patient may rise by about 30% when treated with naltrexone

- Extreme lethargy may occur in patients on thioridazine
- Effects of other opioid-containing medications may be blocked

Always check with BNF (available electronically at www.bnf.org)) or Data Sheet (www.medicines.org.uk)

7. CONTRAINDICATIONS

•

Naltrexone is contraindicated:
• in patients with acute hepatitis or liver failure.
• in patients currently dependent on opioids since an acute withdrawal syndrome may ensue.
• in any patient who has a positive screen for opioids or who has failed the naloxone challenge test.
• in combination with methadone (see section 4.5)
• in conjunction with an opioid containing medication
• in patients who have demonstrated hypersensitivity to to naltrexone hydrochloride or any of the excipients
• severe renal failure

8. INFORMATION TO PATIENT

Patients will be provided with specific information relating to their treatment. Patients should be warned that attempts to overcome the blockade may result in acute opioid intoxication which may be life threatening.

9. DRUG MONITORING

Six monthly liver function tests will need to be undertaken within primary care and any abnormal results discussed with the specialist team.

10. RESPONSIBILITIES OF CLINICIANS INVOLVED

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	• Naltrexone induction must be undertaken by a specialist drug service • LFTs and urinalysis • Naloxone challenge if appropriate • Provide patient with written and verbal information about naltrexone and, in particular, the dangers of overdose on cessation of naltrexone or by attempts to override the antagonist effects • Advise patient to carry a Treatment Card at all times, as treatment with naltrexone renders opioid analgesia ineffective for pain control in the event of emergencies. • Provide regular counselling and support for the patient. • Following the initial six week period, the specialist team drug worker / key worker will liaise with the patient's General Practitioner to discuss the transfer and advise on duration of prescribing (e.g. a period of six months).	• Liaise with the Specialist Team
Monitoring of treatment	• Regular support and advice available to the GP from the appropriate specialist drug services. • Arrangement for continuous patient support and aftercare.	• Six monthly liver function tests and any abnormal results discussed with the specialist team. • Monitor patient for adverse effects • Monitor patients' drug taking • Refer to Specialist where necessary.

Contact details: Specialist Nurse:

During office hours: Out of hours:

APPROVAL PROCESS

Written by:	**Specialist team, HFT**
Consultation process:	**HFT DTC, Dr Ros Davies, Clinical Lead, ReNew Community**
Approved by:	**Medicines Management Interface Group**
Ratified by:	**HERPCSep 15**
Review date:	**September 2018**