North of Tyne Area and Gateshead Prescribing Committee

Naltrexone
Shared Care Guidance

For use in the management of agitation and/or self-injurious behaviour in patients with autism or learning disabilities.

Introduction	The use of naltrexone to reduce agitation and / or self-injurious behaviour is an established treatment for patients with autism or learning disabilities. For this unlicensed indication, prescribing of naltrexone should always be initiated by a specialist, then if appropriate transferred to the patient's GP. Naltrexone's use in this area is supported by a body of physicians and withstands logical analysis, satisfying the Bolam / Bolitho criteria in principle. The use of naltrexone under this arrangement has been approved by Northumberland, Tyne and Wear NHS Trust Medicines Management Committee and the North of Tyne Area and Gateshead Prescribing Committee. Further evidence of naltrexone's use in this indication is also documented in: The Psychotropic Drug Directory, the Maudsley Prescribing Guidelines, and the Frith Prescribing Guidelines for Adults with Learning Disabilities and Martindale the Complete Drug Reference. Usual maintenance dose is 25 – 50mg daily (may be given in one or two divided doses, or on alternate days), doses can range from 12.5mg to a maximum of 100mg daily based on 0.5 to 2mg/glad. Treatment can continue for as long as benefit is maintained. The specialist team will be responsible for treatment discontinuation **Available as:** Nalorex® 50mg tablets, Opizone® 50mg tablets, both film coated scored tablets
Specialist Responsibilities	• Discuss the benefits and side effects of treatment with the patient and carers, informing them that this is an off label use of naltrexone. • Carry out baseline liver function tests in obese and elderly patients. • Initiate and determine response to treatment. • Review patient until stable and suitable for shared care, this should follow dose and drug stabilisation for at least one month. • GPs should not be asked to prescribe naltrexone for pregnant or breast feeding women. • When the patient is stable, complete the shared care request form and send it to the patient's GP. • Review the patient's management and response to treatment every 6 month • Six monthly liver function tests should be carried out by the specialist team in obese (BMI>30) and elderly patients. • 6 monthly reviews by the specialist team to determine response to treatment. • The specialist team will be responsible for treatment discontinuation.
GP Responsibilities	• Notify the specialist promptly if unwilling to participate in the shared care arrangement. • Prescribe naltrexone following dose and drug stabilisation by the specialist. • To liaise with the specialist regarding any adverse drug reaction, including the reporting of any serious adverse drug reaction to the MHRA. • To contact the specialist in the following circumstances: o Sudden deterioration in patient's condition o Patient intolerance or adverse side effects of medication o Non-compliance

	o Unusual prescribing circumstances e.g. initiation of potentially interacting medication, such as opioid analgesics for pain. o Communication failure
Adverse Effects, Precautions, Contraindications	**Contraindications**: Known hypersensitivity to the product, acute hepatitis, severe renal or hepatic impairment, patients currently dependent on opioids. **Cautions**: Impaired liver function. Any necessary liver function tests will be carried out by the specialist team. Because of absence of documented clinical experience naltrexone should only be given to pregnant or breast-feeding women when, in the judgement of the physician, the potential benefits outweigh the possible risks. GPs should not be asked to prescribe in such cases. **Adverse effects**: Difficulty sleeping, anxiety, nervousness, abdominal pain/cramps, nausea and/or vomiting, low energy, joint and muscle pain, and headache Loss of appetite, diarrhoea, constipation, increased thirst, increased energy, feeling down, irritability, dizziness, skin rash, delayed ejaculation, decreased potency, chills, chest pain, increased sweating and increased lacrimation. Rarely: Hepatic dysfunction, suicidal ideation, speech disorders Very rarely: Hallucinations, tremor, idiopathic thrombocytopenia.
Common Drug Interactions	Naltrexone is an opioid antagonist; concomitant administration of naltrexone with an opioid-containing medication should be avoided. 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 and other adverse symptoms and signs.
Communication	**ADHD Specialists** MON – FRI, 09:00 – 17:00 Newcastle and Gateshead CYPS:- 0191 246 6913 (Benton House) North Tyneside CAMHS:- 0191 2196725 (Albion Road Clinic) 0191 200 7435 (Balliol Centre) Northumberland CYPS:- 01670 394 256 (Villa 9, Northgate)

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

Private and Confidential

Naltrexone - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

Specialist Prescriber	Naltrexone……	**Patient details (use hospital label if preferred)**	
Name	……	**Name**	……
Department	……	**Address**	……
Hospital	……		……
Telephone	……	**Postcode**	..... **M/F** ……..
		NHS or Hosp. Reg. No.	…… **DoB** ……..

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement

Drug Name **Naltrexone** **Dose** **Frequency**

Indication

Other Information (if appropriate)

Signed (Specialist Prescriber **Name (print)** **Date**

To be completed by GP

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ❑

or

I ACCEPT the proposed shared care arrangement with the caveats below ❑

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ❑

My caveats / reason(s) for not accepting include:

……..

……..

Signed …… **Name (print)** ..... **Date** ……

(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP