

Produced by: Treatment Review Sub-Group of the Area Drug and Therapeutics Committee

GUIDELINES FOR USE OF ORLISTAT (XENICAL) IN TAYSIDE

Prescription of orlistat is approved only if the following criteria are met.

- Patients should be entered into a 3 month structured weight management programme after being referred to or seen by a health care professional trained in obesity management, including:
 - a hospital or community dietitian;
 - a practice nurse who has undergone suitable training in the provision of diet and lifestyle advice tailored specifically to the use of orlistat (i.e. primarily reduced fat intake).

Note: for this purpose, it is intended to offer future education and training support for practice nurses in Tayside (details to follow).

- Patients have **failed to lose 10% of their body weight** over a **minimum 3 month course of dietetic surveillance** (patients who **have** lost the required weight during this period should continue to receive diet and lifestyle advice and support).

or

If the patient has lost $\geq 7\%$ but less than 10% of body weight by 3 months then the opportunity should be given for a further 3 months attempt with diet alone to achieve the goal of 10% weight loss.

- To ensure some compliance with diet and in order to minimise the risk of GI side effects from treatment, patients should have **lost at least 2.5 kg weight** over any 4 week period within the 3 month assessment programme **before** drug therapy can be prescribed.
- Patients have morbid obesity i.e. BMI >40 (at the time treatment is considered)
or
Those with BMI >35 (at the time treatment is considered) with either one or more co-morbid risk factor, or in need of operation as outlined below.

At least one **co-morbid risk factor** which is of danger to their health and cannot be adequately treated by standard conventional therapy including the following.

Cardiovascular disease i.e. angina, heart failure
Hypertension
Diabetes mellitus
Pituitary problems
Sleep apnoea
Severe hyperlipidaemia
Severe respiratory problems incl. COAD / asthma

- Patients requiring an **operation where the anaesthetist considers the procedure to be hazardous** without weight loss or the **surgeon requires weight loss** to reduce post

operative complications, the risk of which would prevent the operation proceeding, see overleaf for examples.

Examples of surgery which may warrant prior use of orlistat:

Hip replacement and other joint/orthopaedic operations
Coronary artery bypass operations
Aneurysm repair - abdominal and peripheral
Significant abdominal herniation

- Patients with obesity-related infertility problems referred by the Infertility Service
- All patients prescribed orlistat must continue on a diet and be assessed after 3 months therapy. Treatment should be withdrawn in patients who have failed to lose 5% of body weight on the drug at this time.
- If patient does lose $\geq 5\%$ of body weight on the drug then it may be continued (with ongoing monitoring of response/side effects) for the length of time allowed by the licence (presently 2 years) but should cease if;
 - BMI becomes $< 30 \text{ Kg/m}^2$
 - Weight increase $> 5 \text{ Kg}$ from start of drug therapy
- **Major side effects, which must be fully discussed with the patient beforehand:**

Flatus	24%	
Oily discharge PR	27%	
Faecal urgency		22%
Oily stools	20%	
Increased defaecation		11%
Faecal incontinence	8%	

- **Orlistat should not be used in the following situations:**

Concomitant use of fibrate, acarbose, metformin.
Pregnancy and breast feeding
Hepatic impairment and cholestasis
Chronic malabsorption syndrome
Children
Renal impairment (e.g. creatinine $> 150 \text{ micromol/L}$)
Cancer history or susceptibility e.g. breast cancer
Anticoagulated patient (e.g. receiving warfarin)

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SUMMARY AND RECOMMENDATIONS

