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Written March 2005

Review date March 2007
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1. Introduction

A Patient Group Direction (PGD) is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals and approved by the employer, advised by the relevant professional advisory committees. It applies to groups or other service users who may not be individually identified before presentation for treatment.

The purpose of this sample Patient Group Direction (PGD) is to enable pharmacists to provide orlistat to patients, within the setting of a weight management clinic, in accordance with best practice in the management of overweight and obesity. Primary Care Trusts (PCTs) or other commissioning bodies including individual pharmacies may adapt this template to meet their own purposes.

1.1 Obesity, Public Health Community Pharmacy

Introduction

The NHS Plan1 emphasises the need to organise and deliver services according to the needs of patients. To achieve this, Primary Care professionals have been required to work more flexibly for their benefit. PGDs have been introduced as local mechanisms, set up to allow the administration and supply of Prescription Only Medicines (POMs) on the NHS by a defined group of health professionals within a protocol, and with appropriate training.

Obesity is a major public health problem, which is increasing at an alarming rate. Current obesity prevalence is 17% in adult males and 21% in adult females in the UK and one in two of the population are currently overweight2. There are a number of factors involved in the development of overweight and obesity in any individual. The onset of obesity is multifactorial; causes include genetic and environmental reasons, dietary and lifestyle changes, sedentary occupations and pastimes, and socio-economic factors.

Obesity is defined as a Body Mass Index (BMI) ≥ 30 kg/m², with overweight defined as BMI ≥ 25 kg/m². Overweight and obese people are more likely than their leaner counterparts to suffer from heart disease, hypertension, stroke, type II diabetes, arthritis, respiratory disorders, mental health problems, orthopaedic conditions, certain cancers and many other disorders. Death from obesity-related disease increases exponentially with increasing weight. Obesity is the second most common preventable cause of cancer related deaths after smoking3.

In England alone, it is estimated that the cost of treating the consequences of obesity and its wider costs to the economy through lower productivity and lost output is at least £2.6 billion every year4. The role of pharmacy in local weight management services The epidemic of obesity is placing strain on primary care services. Obese and overweight patients are higher users of NHS resources, more frequent visitors to their GP, and more likely to require prescriptions than their leaner counterparts. It is therefore essential to involve pharmacists in the management of these patients.

If pharmacists set up comprehensive weight management clinics, they can have an influence on how obesity is treated, leading to improved weight control without compromising safety.

Pharmacists are very well placed to provide local, high quality, expert advice and support. The Royal College of Physician’s Report(5) on clinical management of overweight and obese patients recognises that use of anti-obesity drugs is justified as adjunctive therapy to conventional diet, exercise and behavioral modification in certain at-risk patients. Given that some pharmacists are already establishing weight management clinics, they are ideally positioned to deliver a PGD supplying orlistat to appropriate patients.
1.2 Objectives of the Orlistat PGD.

The purpose of this document is to provide several functions in the supply of Orlistat under patient group direction: -

- This is a PGD for a pilot weight management service
- To link the PGD to the Wandsworth PCT Obesity Service.
- Supply of Orlistat for patients who are motivated to loose weight on a monthly basis.
- The terms and conditions by which patients can access the community pharmacy weight management service and Orlistat through a PGD.
- To link the Orlistat PGD and community weight management service with Wandsworth PCT Dietician service.
- To signpost patients to weight management services across the PCT

2. Characteristics of Staff authorised to supply Orlistat under this PGD

- Qualifications Required – Registered Pharmacist as Member of the Royal Pharmaceutical Society of Great Britain (MRPharmS). (10)
- Training Requirements and arrangements for continuing education/updating:
  - Manager Responsible- Community Pharmacist Lead
  - Manager responsible for PGD if different from above

3. These Patient Group Directions have been produced for use by community pharmacists in Wandsworth PCT in the following locations:

- A registered Community Pharmacy.
- A GP Practice.
- A healthcare clinic.

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<th>Name:</th>
<th>Job title:</th>
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<tr>
<th>Name:</th>
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<th>Signature and date:</th>
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</table>

These Patient Group Directions become valid on:

These Patient Group Directions become due for review before:

These Patient Group Directions expire on:

4. Terms and conditions of the service

All pharmacists who are allowed to supply Orlistat through Patient Group Directions must have the following requirements in place

- Undergone Wandsworth PCT approved Training.
- Have an understanding of the Wandsworth PCT weight management guidelines (when approved).
- Must be appropriately trained and equipped to provide a weight management service.
- Ensure that the pharmacist can identify suitable patients for the supply of Orlistat under a PGD, and counsel with regard to medication side effects, risks and appropriate dietary advice
5 CLINICAL GOVERNANCE

5.1 Responsibilities

It is the responsibility of the authorised pharmacist to read, understand and work within this PGD. The Community Pharmacist Lead, together with the PCT chief pharmacist and community and PCT pharmacists will review this Patient Group Direction annually or as required, in light of current clinical evidence and practice, and changes to the service.

5.2 Indemnity

The community pharmacist and staff working within this PGD must ensure that their professional indemnity cover is either provided by the National Pharmaceutical Association (NPA) or other organisation, which has confirmed that this activity will be included in their policy. The Trust will accept responsibility only for the accuracy and clinical content of the PGD.

5.3 Monitoring Arrangements for PGD

The community Pharmacist Lead will carry out an audit of the operation of the PGD for Wandsworth PCT at 3-4 months and at the end of September 2005.

5.4 patient selection & entry into the service

Patients chosen for the service will be referred by a Wandsworth PCT Dietician and the participating community pharmacists. Community pharmacists can only select patients with a BMI of between 28 to 35. Patients suitable for the service must fall into the following criteria:
(For more details on BMI see Appendix 5)
- BMI 30-35 with no co-morbidities
- BMI > 28 - 35 with co morbidities
- BMI > 35 at the dietician’s discretion.
- Age 18-75 years
- Informed verbal consent to treatment and adherence to appropriate dietary intake

5.5 Patient

- Must be assessed to be committed and motivated to weight loss and attend all the counselling sessions
- Always advise clients to read the manufacturers literature see Appendix 4.
- Encourage clients to report any side effects straight away.
- Community pharmacists must send details of the patients registration to the patient’s GP and the PCT.
- Where appropriate the participating pharmacist will refer the patient to exercise classes available from the patient’s GP
5.6 Training & CPD

All Pharmacists intending to supply Orlistat under PGD must receive appropriate training. The structure of this training will be determined locally but inclusion of the following procedures is recommended to ensure that the pharmacist:

- Is appropriately trained and equipped to provide specialist weight management advice, and follow-up.
- Can identify suitable patients for supply of Orlistat under a PGD, and counsel with regard to side-effects, risks etc.
- Recognises when patient referral may be required, and maintain regular communication with the patients GP
- Is able to complete necessary paper work.
- Appropriate input from Wandsworth PCT in terms of: local obesity guidelines and Links with the local dietetics service.

Training may be available from a number of sources but interactive workshops and a distance learning pack may be considered suitable options. A suggested programme is appended (Appendix 18).
A College of Pharmacy Practice accredited training module (6 hours) has been developed to assist PCOs with the training of pharmacists.

Accreditation requirements:

In order to be accepted onto the scheme, the pharmacist must feel confident in satisfying the points covered below:

- Be able to identify overweight (with at least one co-morbidity) and obese patients and be able to provide follow-up support.
- Be aware what practical dietary and lifestyle advice could be given to a patient.
- Be able to identify which groups of patients would not be eligible for administration of orlistat under PGD, and why.
- Have a clear understanding of the pathophysiology of obesity and its metabolic consequences.
- Understand the basic principles of obesity as it relates to diabetes and cardiovascular disease.
- Is aware of Wandsworth PCT Obesity guidelines.
- Have a basic understanding of obesity as it relates to other conditions (gall bladder disease, osteoarthritis).
- Be able to perform the appropriate examinations.
- Know and understand how to measure obesity and monitor progress.
- Understand the mode of action and principal therapeutic effects of Orlistat.
- Know the principal contra-indications of orlistat.
- Outline the normal dosage and treatment regimes for the key clinical condition where orlistat is administered.
- Describe the action taken if a patient demonstrates a local allergic reaction to Orlistat.
- Maintain audit data for clinical governance purposes.
- Maintain regular communication with local GP.
5.6 References


7. The Medicines Act (Miscellaneous Provision) 1997 allows client records to be kept electronically.

More references are provided in Appendix 20 to support CPD.
6. PATIENT GROUP DIRECTION

For the supply/administration of Orlistat as part of a pharmacotherapy support to a community pharmacy weight pilot service management service.

6.1. Clinical Conditions to which the PGD applies.

As an aid to a weight management service.
- Patients classified as obese
- Clients are willing to lose weight.

<table>
<thead>
<tr>
<th>Supply outside the terms of the SPC</th>
<th>Orlistat may not be supplied outside the terms of the SPC.</th>
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</thead>
<tbody>
<tr>
<td>Clinical situation for which medicine is to be used</td>
<td>Orlistat is indicated in conjunction with a mildly hypocaloric diet for the treatment of the following groups of clients:</td>
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<tr>
<td></td>
<td>• Clients who are obese (i.e. with a BMI $\geq$ 30kg/m$^2$) but who are actively participating in a weight management programme and who have demonstrated motivation to change dietary behaviour.</td>
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<td>• Clients who are overweight (i.e. BMI $\geq$ 28kg/m$^2$) with one or more co-morbidity, such as hypertension, dyslipidaemia or type 2 diabetes who also are actively participating in a weight management programme and who have demonstrated motivation to change dietary behaviour.</td>
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First line treatment (lifestyle changes) must be followed for at least 3 months before anti-obesity drugs are to be used. Orlistat should be used to support healthy lifestyle and behaviour changes and not in isolation.

Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy.

Treatment with orlistat should be discontinued after six months if patients have been unable to lose at least 10% of the body weight as measured at the start of drug therapy.

Treatment should be reviewed at 6 months.

<table>
<thead>
<tr>
<th>Criteria for inclusion</th>
<th>Clients must be registered with a GP based within Wandsworth and be willing to accept treatment from a pharmacist.</th>
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<tr>
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<td>• BMI 30-35 with no co-morbidities</td>
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<td>• BMI &gt; 28 - 35 + co morbidities</td>
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<td>• BMI &gt; 35 at the dieticians discretion.</td>
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<td>• Age 18-75 years</td>
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<td>• First line treatment (lifestyle changes) must be followed for at least 3 months before anti-obesity drugs are to be used.</td>
</tr>
<tr>
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<td>• Informed verbal consent to treatment and adherence to appropriate weight management programme.</td>
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<td>• Possible referral from local dietician</td>
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</table>
### Criteria for exclusion

- **BMI < 28 kg/m²**
- Age under 18 years or over 74 years
- Refusal of consent
- Known hypersensitivity to orlistat or its excipients
- Current cholestasis
- Breast feeding or pregnancy
- Concurrent administration of cyclosporin, acarbose, sibutramine or other weight loss agents
- Chronic malabsorption syndrome
- Concurrent administration of insulin*
- Post bariatric surgery
- Patient is already receiving Orlistat by prescription and part of a weight management service.
- Inadequate weight loss
  - < 5% weight loss within three months of initiation of treatment
  - < 10% cumulative weight loss at six months after initiation of treatment
  - Treatment period has exceeded one year/two years
- Discontinue pharmacotherapy but carry on with the weight management service through counselling and health promotion

*Within the terms of its SPC, orlistat may be used in patients who are on insulin. However, there may be an increased risk of hypoglycaemia in these patients as weight loss can lead to improvement in glycaemic control. These patients therefore warrant special care so that the dose of insulin may be appropriately monitored.

N.B. Vitamins and beta-carotene: Decreases in the absorption of vitamins D, E and beta-carotene should be taken into account.

Patients not eligible for treatment under this protocol will be recommended to refer to their GP for further assessment and advice.

### Criteria for referral

Clients should be referred to their GP:

- When client is considered eligible for orlistat therapy under a weight loss programme, but supply through pharmacy is not recommended through the exclusion criteria

This might include any of the conditions referred to as exclusion criteria above, but also:

- Previously unrecognised co-morbidities:
  - Random blood glucose > 9mmol/l
  - BP > 140/85 or BP > 130/80 (known diabetes) on three consecutive occasions
  - Total cholesterol (random) > 5mmol/L. Referral for advice, but accept re-referral once cholesterol is dealt with by GP
  - Urine test analysis – positive for glucose, protein or blood
- Uncontrolled symptoms
- Uncontrolled symptoms of other illnesses that are a cause for concern e.g. mental health, orthopaedic problems
| Dosage and method of administration | The recommended dose of orlistat is one 120mg capsule which should be taken immediately before, during or up to one hour after each main meal (2-3 times daily). If a meal is missed or contains no fat, the dose of orlistat should be omitted. See Appendix 1 and 2 for individual product details. |
| Period of administration | This will be determined by the pharmacist, but will normally follow the following guidelines:  
  • First line treatment (lifestyle changes) must be followed for at least 3 months before anti-obesity drugs are to be used.  
  • Administer Orlistat for a period of only 4 weeks at a time.  
  • Treatment with Orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy  
  • Treatment with orlistat should be discontinued after 24 weeks if patients have been unable to lose at least 10% of the body weight as measured at the start of therapy  
  • Client should undergo a review with GP at 12 months  
  Treatment with orlistat should not been continued beyond 24 months |
| Drug interactions | The concomitant administration of orlistat is not recommended with the following:  
*see Appendix 2 section 4.5 Summary of product characteristics.*)  
  • Acarbose  
  • Other Anorectic (weight loss) drugs  
  • Amiodarone-Administration in patients taking warfarin or other anticoagulants, international normalised ratio (INR) values should be monitored, therefore these patients should be referred to the GP for INR monitoring  
  Cyclosporin plasma levels should be monitored when orlistat is co-administered. For that reason it is recommended that patients on cyclosporin should not receive orlistat under this PGD. |
| Side effects | Adverse reactions to orlistat are largely gastrointestinal in nature:  
  • Oily spotting from rectum  
  • Flatus with discharge  
  • Faecal urgency  
  • Fatty/oily stool  
  • Oily evacuation  
  • Increased defaecation  
  • Faecal incontinence  
  Other treatment-emergent adverse events that occurred at a frequency of >2% and with an incidence > 1% above placebo are detailed in Appendix 1. |
### Advice to client
The advice to clients should include specific product advice, in addition to general advice relating to physical activity and diet:

- Orlistat must be taken with recommended healthy balanced diet containing less than 30% energy (calories) from fat.
- 1 x 120mg capsule orlistat should be taken immediately before, during or up to 1 hour after each main meal (2-3 times daily).
- If a meal is missed or contains no fat, the dose of orlistat should be omitted.
- The capsules should be stored in a cool place.

Recommend that the client read the appropriate enclosed information leaflet, which should be given to the client at the time of supply. This gives details of how to take orlistat and how to modify dietary intake appropriately.

The client should register with MAP (Motivation: Advice: Proactive support), the Roche sponsored freephone supportline, and provide them with some information about the service: 0800 731 7138.

### Follow-up
Patients should be registered on MAP.

Follow-up appointments should be made monthly for the first six months for clients with no co-morbidities, and 3 monthly thereafter.

Those clients with co-morbidities should be assessed at least monthly throughout the treatment period, under the weight management programme.

BMI, waist circumference and arm circumference should be assessed at each follow-up appointment.

### Adverse outcomes
Clients must be advised to follow a healthy balanced dietary intake with no more than 30% of calories from fat, while taking orlistat.

If the caloric intake exceeds 30% of energy from fat, then patients may experience gastrointestinal side effects such as:

- Oily spotting from rectum
- Flatus with discharge
- Faecal urgency
- Fatty/oily stool
- Oily evacuation
- Increased defaecation
- Faecal incontinence

Clients should be advised about this at the time of dispensing orlistat and advised that, providing a balanced diet with appropriate fat intake is followed, these treatment effects can be managed and are less likely to occur. Any event of this nature suggests that the dietary intake has been inappropriate and may reflect hidden fat in the diet, alerting the client to this possibility.

Clients should be able to modify their dietary intake appropriately to avoid these treatment effects.

[For the pharmacist they are an indication that the client is not following the recommended low fat diet and appropriate dietary advice and follow up should be made available.]
Facilities and supplies | Orlistat should be stored in a cool place.

Orlistat when issued is to be labelled with the date of dispensing and the client’s name, according to pharmacy procedures on the patient medication record system. A mechanism should be put in place to ensure that the patient record acknowledges the supply of orlistat under PGD. Prescription charges need to be collected in the usual manner, and exempt patients will need to fill in a consent form (See appendix 11).

Management and monitoring | The pharmacist will need to obtain the name, address, and date of birth of the client and record these details for submission monthly to [xxx name] to arrange payment (See Appendix 7).

Informed consent | Client information relating to the supply of orlistat under PGD has to be passed to other health service organisations, such as a client’s GP or the local NHS commissioning body, for a variety of purposes such as audit or payment.

The client’s informed consent must be obtained before information can be passed to their GP (See Appendix 10).

Details of record keeping for audit purposes | The pharmacist must keep a record of the consultation for at least two years’, and the following documents in particular:

- The letter of recommendation to supply, or a copy should be kept with the client’s records
- The Client registration form (See Appendix 7) to be completed and signed by the pharmacist and sent to the GP
- Details of product(s) supplied, invoices and prescription charges collected should be recorded as required for audit purposes
- Audit forms should be completed and returned as required

Characteristics of staff authorised to take responsibility for supply and administration | Member of the Royal Pharmaceutical Society of Great Britain and a practising community pharmacist.

Have attended the training session on weight management.

Have completed the self-directed learning package on administration of orlistat.

6.2 Action if excluded

When Orlistat is thought to be appropriate but supply through pharmacy is not recommended then the client should be referred to a GP. This might include any of the conditions referred to as exclusion criteria above but also:

- Offer the patient non-pharmacotherapy weight loss i.e. counselling.
- Refer the patient back to a dietician if appropriate and if patient has one or more co-morbidities.
- Refer to GP with advice and recommendations.
7.0 SERVICE SUMMARY

Patients that meet the inclusion criteria (see 5.4) can access the service by referral from a dietician or a community pharmacist. The length of this pilot service is 6 months. The patient will be expected to complete a consent form (appendix 8) and a Questioning Protocol (appendix 9).

During the course of the service the pharmacist will complete the patient management form (Appendix 10). Pharmacist will provide invoicing information (appendix 13) and take monthly prescription charges for those patients who pay.

**Months 1-3 consists of 2 fortnightly patient visits a month for 3 months**
- The first appointment will involve taking patient history and clinical readings.
- Subsequent visits will consist of taking BMI readings and issuing advice.

During the first 3 months patients must complete a Quality of life questionnaire (Appendix 11). This will be required as part of the evaluation of this service (This should be completed at or before the first visit)

**Months 4-6 consist of monthly visits**
- Taking BMI readings and height

Pharmacists counsel patients, review lifestyle and provide support for the patients. Patients are encouraged to visit their chosen pharmacy and go in for a weight measurement on a weekly basis.

Patients, who suffer from diabetes, hypertension or coronary heart disease, would be encouraged to bring clinical readings from their GP appointments or readings they have taken themselves.

The participating community pharmacists would hold patient files, which patients could access.

During the last month of the service patients will be expected to fill in a patient satisfaction questionnaire (Appendix 12), which will contribute to the evaluation.

**7.1 Evaluation issues**
The pilot service will be evaluated. The following criteria should be considered during the evaluation of the service:-
- Good GP/pharmacist/dietician interaction
- Patient weight loss and health improvement
- Patient satisfaction
- Appropriate use of pharmacotherapy

**Characteristics of a reputable weight management**
Generally speaking, a good weight management service will:
- Emphasise improved health, such as lower blood cholesterol and reduced risk of diabetes and heart disease.
- Focus on the loss of body fat, not just weight.
- Include regular exercise.
- Advise against a daily energy intake of less than 5000Kj.
- Recommend a gradual weight loss of around one kilogram per week.
- Appreciate input from a doctor or health care professional.
- Advise on how to improve long term eating and exercise habits.
8. Patient Group Direction Agreement

I have undertaken the one-day community pharmacy weight management training and the patient group direction training for Orlistat, which practitioners must undertake before being authorised to supply Orlistat under this Patient Group Direction (PGD).

I understand that by agreeing to act as an approved practitioner under the patient group direction and service level agreement I am adjusting my scope of professional practice.

I will adhere to the Clinical Governance procedures of this Patient Group Direction (section 5).

To be signed by the Community pharmacy who agrees to use the PCG(s) marked below and his or her manager

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<th>PGD number</th>
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I hereby agree that I have read and understood the Patient Group Direction(s) and I am competent to practice accordingly.

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<tr>
<th>Community Pharmacist</th>
<th>Signature and date</th>
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<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Manager</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Signature and date</td>
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This/these P.G.D/s expire on: September 2006 and may be amended prior to that date.
This service specification has been authorised by
Di Caufield-Stoker Director of Clinical Governance.

On behalf of: Wandsworth PCT
Signature:
Date: ____________________________

Countersigned by:
Name: Dr David Finch, Medical Director
On behalf of: Wandsworth PCT
Signature:
Date: ____________________________

Countersigned by:
Name: Norman Evans Chief Pharmacist
On behalf of: Wandsworth PCT
Signature:
Date: ____________________________

Review date March 2007

Enquiries relating to this PGD should be addressed to:

David Tamby Rajah Community Pharmacist Lead,
WANDSWORTH PCT,
2nd floor, Teak tower,
Springfield University Hospital
61 Glenburnie Rd,
London SW17 7DJ
## MANAGER’S RECORD

<table>
<thead>
<tr>
<th>PGD(s)</th>
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<tr>
<td>Name of community Pharmacist</td>
<td>Pharmacy</td>
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## CHECK LIST FOR LOCAL CLINICAL MANAGER:

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<th>PGD(s) for:</th>
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| PGD agreement(s) signed by Community Pharmacist and Community Pharmacist Lead: |  |
| List of sites where PGD’s are held is complete: | Electronic copy on Central Register. Hard copy archived in a central file. Community Pharmacist retains a copy. |

| Arrangements for continuing education in place: | Update accredited training as required. |

| Audit mechanism in place: | Including details of how individuals given a medicine under PGD and the record of this event can be traced |

| Review date: | September 2006 |
APPENDIX 1 National Institute for Clinical Excellence (NICE) Guidance on Orlistat

The NICE guidance on Orlistat states:
Orlistat should only be prescribed for people who have lost at least 2.5 kg in weight by dietary control and increased physical activity alone in the month prior to the first prescription*1 and meet the following criteria:

- A BMI of 28 kg/m² or more in the presence of significant co-morbidities, which persist despite standard treatment. (e.g. Type 2 diabetes, hypertension and/or hypercholesterolaemia).
- A BMI of 30 kg/m² or more with no associated co-morbidities.
- Be between the ages of 18 and 75 years.
- Be offered concomitant advice, support and counselling on diet, physical activity and behavioural strategies.
- Continuation of this therapy beyond three months should be supported by evidence of a loss of at least a further 5% of body weight from the start of drug treatment.
- Continuation of this therapy beyond six months should be supported by evidence of a cumulative weight loss of at least 10% of body weight from the start of drug treatment*2.
- Treatment should be reviewed at 12 months, and never continued beyond 24 months*3.

*1 This restriction has been removed from the product licence
*2 This is not stated in the product licence
*3 There is no restriction on duration of treatment according to the product licence

The NICE guidance also provides advice on implementation of pharmacotherapy:

- Orlistat must be viewed as only one of a number of approaches in tackling the growing problem of obesity. In order to facilitate the appropriate use of pharmacological management of obesity, training of a sufficient number of primary care staff (mostly practice nurses) will be necessary to carry out initial patient assessments, and to provide continuing advice and support for patients before, during and after drug treatment.
- Obesity Action Plans, which recognise the extent of the burden of obesity and formulate ways of targeting key groups, should be set up at local level. These plans should especially prioritise those who may gain most benefit from therapy, and offer systematic weight management services.
- There will be some ‘knock-on’ effects to the secondary and tertiary level, as more patients with obesity are referred on.
- To enable clinicians to audit their own compliance with this guidance it is recommended that treatment plans be recorded for each patient.
- This information should be incorporated into local audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in routine electronic record keeping systems used in hospitals and them multi-disciplinary groups working in support of people with obesity.
APPENDIX 2: Summary of Product Characteristics UK/Ireland

1. NAME OF THE MEDICINAL PRODUCT

XENICAL 120 mg hard capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 120 mg orlistat.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard.
The capsule has a turquoise cap and turquoise body bearing the imprint of “ROCHE XENICAL 120”.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

XENICAL is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m², or overweight patients (BMI ≥ 28 kg/m²) with associated risk factors.

Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of drug therapy.

4.2 Posology and method of administration

Adults

The recommended dose of orlistat is one 120 mg capsule taken with water immediately before, during or up to one hour after each main meal. If a meal is missed or contains no fat, the dose of orlistat should be omitted.

The patient should be on a nutritionally balanced, mildly hypocaloric diet that contains approximately 30% of calories from fat. It is recommended that the diet should be rich in fruit and vegetables. The daily intake of fat, carbohydrate and protein should be distributed over three main meals.

Doses of orlistat above 120 mg three times daily have not been shown to provide additional benefit. The effect of orlistat results in an increase in faecal fat as early as 24 to 48 hours after dosing. Upon discontinuation of therapy, faecal fat content usually returns to pre-treatment levels, within 48 to 72 hours.

Special populations

The effect of orlistat in patients with hepatic and/or renal impairment, children and elderly patients has not been studied. Orlistat is not intended to be used in children.
4.3 Contraindications

- Chronic malabsorption syndrome
- Cholestasis
- Breast-feeding
- Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and special precautions for use

In clinical trials, the decrease in bodyweight with orlistat treatment was less in type II diabetic patients than in non-diabetic patients. Antidiabetic drug treatment may have to be closely monitored when taking orlistat.

Co-administration of orlistat with cyclosporine is not recommended (see section 4.5).

Patients should be advised to adhere to the dietary recommendations they are given (see section 4.2 Posology and method of administration). The possibility of experiencing gastrointestinal events (see section 4.8 Undesirable effects) may increase when orlistat is taken with a diet high in fat (e.g. in a 2000 kcal/day diet, > 30% of calories from fat equates to > 67 g of fat). The daily intake of fat should be distributed over three main meals. If orlistat is taken with a meal very high in fat, the possibility of gastrointestinal adverse events may increase.

4.5 Interaction with other medicinal products and other forms of interaction

Cyclosporine
A decrease in cyclosporine plasma levels has been observed in a drug-drug-interaction study and also reported in several cases, when orlistat was administered concomitantly. This can lead to a decrease of immunosuppressive efficacy. Therefore the combination is not recommended (see section 4.4). However, if such concomitant use is unavoidable, more frequent monitoring of cyclosporine blood levels should be performed both after addition of orlistat and upon discontinuation of orlistat in cyclosporine treated patients. Cyclosporine blood levels should be monitored until stabilised.

Acarbose
In the absence of pharmacokinetic interaction studies, the concomitant administration of orlistat with acarbose should be avoided.

Oral Anticoagulants
When warfarin or other anticoagulants are given in combination with orlistat, international normalised ratio (INR) values should be monitored.

Fat soluble vitamins
Treatment with orlistat may potentially impair the absorption of fat-soluble vitamins (A, D, E and K).

The vast majority of patients receiving up to four full years of treatment with orlistat in clinical studies had vitamin A, D, E and K and beta-carotene levels that stayed within normal range. In order to ensure adequate nutrition, patients on a weight control diet should be advised to have a diet rich in fruit and vegetables and use of a multivitamin supplement could be considered. If a multivitamin supplement is recommended, it should be taken at least two hours after the administration of orlistat or at bedtime.
Amiodarone
A small decrease in plasma levels of amiodarone, when given as a single dose, has been observed in a limited number of healthy volunteers who received orlistat concomitantly; in patients receiving amiodarone treatment, the clinical relevance of this effect remains unknown but may be of minor relevance. However, in patients receiving concomitant amiodarone treatment, reinforcement of clinical and ECG monitoring is warranted.

Lack of interactions
No interactions with amitriptyline, atorvastatin, biguanides, digoxin, fibrates, fluoxetine, losartan, phenytoin, oral contraceptives, phentermine, pravastatin, nifedipine Gastrointestinal Therapeutic System (GITS), nifedipine slow release, sibutramine or alcohol have been observed. The absence of these interactions has been demonstrated in specific drug-drug-interaction studies.

4.6 Pregnancy and lactation
For orlistat no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see 5.3, Preclinical safety data). Caution should be exercised when prescribing to pregnant women.

As it is not known whether orlistat is secreted into human milk, orlistat is contra-indicated during breast-feeding.

4.7 Effects on ability to drive and use machines
Xenical has no influence on the ability to drive and use machines.

4.8 Undesirable effects
Adverse reactions to orlistat are largely gastrointestinal in nature. The incidence of adverse events decreased with prolonged use of orlistat.
The following table of undesirable effects (first year of treatment) is based on adverse events that occurred at a frequency of > 2 % and with an incidence ≥ 1 % above placebo in clinical trials of 1 and 2 years duration:

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Event</th>
<th>XENICAL</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Infections and Infestations</td>
<td>Very common (≥10%): Influenza</td>
<td>39.7 %</td>
<td>36.2 %</td>
</tr>
<tr>
<td>• Metabolism and Nutrition Disorders</td>
<td>Very common (≥10%): Hypoglycaemia*</td>
<td>13.0 %</td>
<td>10.0 %</td>
</tr>
<tr>
<td>• Psychiatric Disorders</td>
<td>Common (1 - &lt;10%): Anxiety</td>
<td>4.7 %</td>
<td>2.9 %</td>
</tr>
<tr>
<td>• Nervous System Disorders</td>
<td>Very common (≥10%): Headache</td>
<td>30.6 %</td>
<td>27.6 %</td>
</tr>
<tr>
<td>• Respiratory, Thoracic and Mediastinal Disorders</td>
<td>Very common (≥10%): Upper respiratory infection</td>
<td>38.1 %</td>
<td>32.8 %</td>
</tr>
<tr>
<td></td>
<td>Common (1 - &lt;10%): Lower respiratory infection</td>
<td>7.8 %</td>
<td>6.6 %</td>
</tr>
<tr>
<td>• Gastrointestinal Disorders</td>
<td>Very common (≥10%): Oily spotting from the rectum</td>
<td>26.6 %</td>
<td>1.3 %</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain/discomfort</td>
<td>25.5 %</td>
<td>21.4 %</td>
</tr>
<tr>
<td></td>
<td>Flatus with discharge</td>
<td>23.9 %</td>
<td>1.4 %</td>
</tr>
<tr>
<td></td>
<td>Faecal urgency</td>
<td>22.1 %</td>
<td>6.7 %</td>
</tr>
<tr>
<td></td>
<td>Fatty/oily stool</td>
<td>20.0 %</td>
<td>2.9 %</td>
</tr>
<tr>
<td></td>
<td>Flatulence</td>
<td>16.0 %</td>
<td>13.1 %</td>
</tr>
<tr>
<td></td>
<td>Liquid stools</td>
<td>15.8 %</td>
<td>11.4 %</td>
</tr>
<tr>
<td></td>
<td>Oily evacuation</td>
<td>11.9 %</td>
<td>0.8 %</td>
</tr>
<tr>
<td></td>
<td>Increased defaecation</td>
<td>10.8 %</td>
<td>4.1 %</td>
</tr>
<tr>
<td></td>
<td>Common (1 - &lt;10%): Soft stools</td>
<td>8.8 %</td>
<td>6.8 %</td>
</tr>
<tr>
<td></td>
<td>Faecal incontinence</td>
<td>7.7 %</td>
<td>0.9 %</td>
</tr>
<tr>
<td></td>
<td>Abdominal distension*</td>
<td>6.0 %</td>
<td>4.0 %</td>
</tr>
<tr>
<td></td>
<td>Rectal pain/discomfort</td>
<td>5.2 %</td>
<td>4.0 %</td>
</tr>
<tr>
<td></td>
<td>Tooth disorder</td>
<td>4.3 %</td>
<td>3.1 %</td>
</tr>
<tr>
<td></td>
<td>Gingival disorder</td>
<td>4.1 %</td>
<td>2.9 %</td>
</tr>
<tr>
<td>• Renal and Urinary Disorders</td>
<td>Common (1 - &lt;10%): Urinary tract infection</td>
<td>7.5 %</td>
<td>7.3 %</td>
</tr>
<tr>
<td>• Reproductive System and Breast Disorders</td>
<td>Common (1 - &lt;10%): Menstrual irregularity</td>
<td>9.8 %</td>
<td>7.4 %</td>
</tr>
<tr>
<td>• General Disorders and Administration Site Conditions</td>
<td>Common (1 - &lt;10%): Fatigue</td>
<td>7.2 %</td>
<td>6.4 %</td>
</tr>
</tbody>
</table>

* only unique treatment adverse events that occurred at a frequency of > 2 % and with an incidence ≥ 1 % above placebo in obese type 2 diabetic patients.

In a 4 year clinical trial, the general pattern of adverse event distribution was similar to that reported for the 1 and 2 year studies with the total incidence of gastrointestinal related adverse events occurring in year 1 decreasing year on year over the four year period.
The following table of undesirable effects is based on post-marketing spontaneous reports:

<table>
<thead>
<tr>
<th>Immune System Disorders</th>
<th>Gastrointestinal disorders</th>
<th>Hepato-Biliary Disorders</th>
<th>Skin and subcutaneous tissue disorders</th>
<th>Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare (0.01 - &lt; 0.1 %): Hypersensitivity (e.g. pruritus, rash, urticaria, angioedema, bronchospasm and anaphylaxis).</td>
<td>Very rare (&lt; 0.01 %): Diverticulitis.</td>
<td>Very rare (&lt; 0.01 %): Cholelithiasis.</td>
<td>Very rare (&lt; 0.01 %): Bullous eruptions.</td>
<td>Very rare (&lt; 0.01 %): Increase in liver transaminases and in alkaline phosphatase. Decreased prothrombin, increased INR and unbalanced anticoagulant treatment resulting in variations of haemostatic parameters have been reported in patients treated with anticoagulants in association with orlistat.</td>
</tr>
</tbody>
</table>

4.9 Overdose

Single doses of 800 mg orlistat and multiple doses of up to 400 mg three times daily for 15 days have been studied in normal weight and obese subjects without significant adverse findings. In addition, doses of 240 mg tid have been administered to obese patients for 6 months. The majority of orlistat overdose cases received during post-marketing reported either no adverse events or adverse events that are similar to those reported with recommended dose.

Should a significant overdose of orlistat occur, it is recommended that the patient be observed for 24 hours. Based on human and animal studies, any systemic effects attributable to the lipase-inhibiting properties of orlistat should be rapidly reversible.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Anti obesity agent, ATC code A08A B01.

Orlistat is a potent, specific and long-acting inhibitor of gastrointestinal lipases. It exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with the active serine site of the gastric and pancreatic lipases. The inactivated enzyme is thus unavailable to hydrolyse dietary fat, in the form of triglycerides, into absorbable free fatty acids and monoglycerides.

In the 2-year studies and the 4-year study, a hypocaloric diet was used in association with treatment in both the orlistat and the placebo treated groups.

Pooled data from five 2 year studies with orlistat and a hypocaloric diet showed that 37 % of orlistat patients and 19 % of placebo patients demonstrated a loss of at least
5 % of their baseline body weight after 12 weeks of treatment. Of these, 49 % of orlistat treated patients and 40 % of placebo treated patients went on to lose ≥ 10 % of their baseline body weight at one year. Conversely, of patients failing to demonstrate a loss of 5 % of their baseline body weight after 12 weeks of treatment, only 5 % of orlistat treated patients and 2 % of placebo treated patients went on to lose ≥ 10 % of their baseline body weight at one year. Overall, after one year of treatment, the percentage of patients taking 120 mg orlistat who lost 10 % or more of their body weight was 20 % with orlistat 120 mg compared to 8 % of patients taking placebo. The mean difference in weight loss with the drug compared to placebo was 3.2 kg.

Data from the 4-year XENDOS clinical trial showed that 60 % of orlistat patients and 35 % of placebo patients demonstrated a loss of at least 5 % of their baseline body weight after 12 weeks of treatment. Of these, 62 % of orlistat treated patients and 52 % of placebo treated patients went on to lose ≥ 10 % of their baseline body weight at one year. Conversely, of patients failing to demonstrate a loss of 5 % of their baseline body weight after 12 weeks of treatment, only 5 % of orlistat treated patients and 4 % of placebo treated patients went on to lose ≥ 10 % of their baseline body weight at one year. After 1 year of treatment, 41 % of the orlistat treated patients versus 21 % of placebo treated patients lost ≥ 10 % of body weight with a mean difference of 4.4 kg between the two groups. After 4 years of treatment 21 % of the orlistat treated patients compared to 10 % of the placebo treated patients had lost ≥ 10 % of body weight, with a mean difference of 2.7 kg.

More patients on orlistat or placebo lost baseline body weight of at least 5 % at 12 weeks or 10 % at one year in the XENDOS study than in the five 2-year studies. The reason for this difference is that the five 2-year studies included a 4-week diet and placebo lead-in period during which patients lost on average 2.6 kg prior to commencing treatment.

Data from the 4-year clinical trial also suggested that weight loss achieved with orlistat delayed the development of type 2 diabetes during the study (cumulative diabetes cases incidences: 3.4 % in the orlistat group compared to 5.4 % in the placebo-treated group). The great majority of diabetes cases came from the subgroup of patients with impaired glucose tolerance at baseline, which represented 21 % of the randomised patients. It is not known whether these findings translate into long-term clinical benefits.

In obese type 2 diabetic patients insufficiently controlled by antidiabetic agents, data from four one-year clinical trials showed that the percentage of responders (≥ 10 % of body weight loss) was 11.3 % with orlistat as compared to 4.5 % with placebo. In orlistat-treated patients, the mean difference from placebo in weight loss was 1.83 kg to 3.06 kg and the mean difference from placebo in HbA1c reduction was 0.18 % to 0.55 %. It has not been demonstrated that the effect on HbA1c is independent from weight reduction.

5.2 Pharmacokinetic properties

Absorption:
Studies in normal weight and obese volunteers have shown that the extent of absorption of orlistat was minimal. Plasma concentrations of intact orlistat were non-measurable (< 5 ng/ml) eight hours following oral administration of orlistat.
In general, at therapeutic doses, detection of intact orlistat in plasma was sporadic and concentrations were extremely low (< 10 ng/ml or 0.02 µmol), with no evidence of accumulation, which is consistent with minimal absorption.

**Distribution:**
The volume of distribution cannot be determined because the drug is minimally absorbed and has no defined systemic pharmacokinetics. *In vitro* orlistat is > 99 % bound to plasma proteins (lipoproteins and albumin were the major binding proteins). Orlistat minimally partitions into erythrocytes.

**Metabolism:**
Based on animal data, it is likely that the metabolism of orlistat occurs mainly within the gastrointestinal wall. Based on a study in obese patients, of the minimal fraction of the dose that was absorbed systemically, two major metabolites, M1 (4-member lactone ring hydrolysed) and M3 (M1 with N-formyl leucine moiety cleaved), accounted for approximately 42 % of the total plasma concentration.

M1 and M3 have an open beta-lactone ring and extremely weak lipase inhibitory activity (1000 and 2500 fold less than orlistat respectively). In view of this low inhibitory activity and the low plasma levels at therapeutic doses (average of 26 ng/ml and 108 ng/ml respectively), these metabolites are considered to be pharmacologically inconsequential.

**Elimination:**
Studies in normal weight and obese subjects have shown that faecal excretion of the unabsorbed drug was the major route of elimination. Approximately 97 % of the administered dose was excreted in faeces and 83 % of that as unchanged orlistat. The cumulative renal excretion of total orlistat-related materials was < 2 % of the given dose. The time to reach complete excretion (faecal plus urinary) was 3 to 5 days. The disposition of orlistat appeared to be similar between normal weight and obese volunteers. Orlistat, M1 and M3 are all subject to biliary excretion.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

In animal reproductive studies, no teratogenic effect was observed. In the absence of a teratogenic effect in animals, no malformative effect is expected in man. To date, active substances responsible for malformations in man have been found teratogenic in animals when well-conducted studies were performed in two species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule filling:
- Microcrystalline cellulose (E 460),
- sodium starch glycollate,
- povidone (E 1201),
- sodium lauryl sulphate and
talc.
Capsule shell:
Gelatine,
indigo carmine (E132),
titanium dioxide (E171) and
edible printing ink (black iron oxide, soya lecithin, polydimethylsiloxane, shellac).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

For blister strips: Do not store above 25°C. Store in original package in order to
protect from moisture.

For glass bottles with desiccant: Do not store above 30°C. Keep the container tightly
closed in order to protect from moisture.

6.5 Nature and contents of container

PVC/PE/PVDC blisters and glass bottles with desiccant containing 21, 42 and 84
hard capsules.
Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Roche Registration Limited
40 Broadwater Road
Welwyn Garden City
Hertfordshire
AL7 3AY
United Kingdom.

8. MARKETING AUTHORISATION NUMBERS

EU/1/98/071/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 July 1998 / 29 July 2003

10. DATE OF REVISION OF THE TEXT

September 2004   P9791301/904:
## APPENDIX 3: WEIGHT MANAGEMENT PROTOCOL

<table>
<thead>
<tr>
<th>Session</th>
<th>Measurements</th>
<th>Topic</th>
<th>Take Home</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(10-15 mins)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Week 0</strong></td>
<td>• Weight</td>
<td>• Weight loss history</td>
<td>• Register on MAP for pre-drug phase – use fax back form</td>
</tr>
<tr>
<td></td>
<td>• BMI</td>
<td>• Benefits of weight maintenance and weight loss</td>
<td>• Patient held record card</td>
</tr>
<tr>
<td></td>
<td>• Waist circumference</td>
<td>• ‘Why do you want to lose weight?’</td>
<td>• BOGH Leaflet</td>
</tr>
<tr>
<td></td>
<td>• Arm Circumference</td>
<td>• Do you feel prepared to make changes to your lifestyle?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Energy Balance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Agree realistic goals: 1xDietary 1xPhysical Activity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Weight maintenance / 1lb-2lb per week weight loss</td>
<td></td>
</tr>
<tr>
<td><strong>Session 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(10 mins)</td>
<td>• Weight</td>
<td>• Discuss principles of a balanced diet</td>
<td>• blank Food Diary</td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
<td>• BMI</td>
<td>• Importance of including a variety of foods</td>
<td>• Food Diary – tips on how to use</td>
</tr>
<tr>
<td></td>
<td>• Waist Circumference</td>
<td>• Promote a low fat, high fibre diet</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Arm Circumference</td>
<td>• Calories per nutrient</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Review previous goals &amp; set two new ones</td>
<td></td>
</tr>
<tr>
<td><strong>Session 3</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(10-15 mins)</td>
<td>• Weight</td>
<td>• Examine food diary using principles of BOGH</td>
<td>• 10 tips for healthy eating leaflet</td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
<td>• BMI</td>
<td>• Portion control</td>
<td>• Refer to GP for pharmacotherapy, if</td>
</tr>
<tr>
<td></td>
<td>• Waist Circumference</td>
<td>• Further support needed?</td>
<td>appropriate</td>
</tr>
</tbody>
</table>
| Session 4  | (10 mins)  | Week 6 | • Weight  
• BMI  
• Waist Circumference | • Discuss exercise & physical activity-refer to leaflet  
• Emphasise Energy Balance  
• Discuss F. I. T. T.  
• Review previous goals & set two new ones | • Register on MAP for full service if pharmacotherapy prescribed – fax through registration.  
• Physical Activity leaflet |
|---|---|---|---|---|---|
| Session 5  | Review of progress (10-15 mins)  
Week 8 (2 months) | • Weight  
• BMI  
• Waist Circumference  
• Arm Circumference | • Review progress – assess motivation  
• Check understanding of dietary change  
• Review progress with pharmacotherapy if prescribed  
• Change in waist circumference ?  
• Review previous goals & set two new ones | |
| Session 6  | (10 mins)  
Week 10 | • Weight  
• BMI  
• Waist Circumference  
• Arm Circumference | • Food labels, Shopping & Nutritional Claims  
• Ask patient to cut out labels for next session  
• Review previous goals & set two new ones | • Food label leaflet & nutritional claims leaflet |
| Session 7  | (10 mins)  
Week 12 (3 months) | • Weight  
• BMI  
• Waist Circumference  
• Arm Circumference | • Examine food labels and discuss  
• Discuss Eating out & Take aways  
• Review previous goals & set two new ones | • Shopping tips leaflet & great meal time tips leaflet |
| Session 8  | Review of progress (10-15 mins)  
Week 16 (4 months) | • Weight  
• BMI  
• Waist Circumference  
• Arm Circumference | • Review progress – assess motivation  
• Discuss maintaining motivation & plateau  
• Review progress with pharmacotherapy if prescribed (3 month on pharmacotherapy – ensure weight loss seen)  
• Change in waist circumference ? | • Recipe Adaptation leaflet |
**Session 9**  
(10 mins)  
**Week 20 (5 months)**  
- Weight  
- BMI  
- Waist Circumference  
- Arm Circumference  
- Discuss topics as required by patient  
- Review previous goals & set two new ones

**Session 10**  
Review of progress  
(10-15 mins)  
**Week 24 (6 months)**  
- Weight  
- BMI  
- Waist Circumference  
- Arm Circumference  
- Weight Maintenance  
- Keeping the weight off  
- Review progress with pharmacotherapy  
- Change in waist circumference ?  
- Improvement in diabetic indicators ?  
- Review previous goals & set two new ones

 Recommend patient is managed on Weight Management Protocol as team, with chemist assistants taking the measurements and giving low level of advice and pharmacist reviewing patient progress and considering appropriate use of pharmacotherapy. As a minimum pharmacists should see the patient for part of sessions 1, 3, 5, 8, & 10.
APPENDIX 4: Patient Information
KEY POINTS TO REMEMBER

Please ensure that you read this document carefully, in addition to the Patient Information Leaflet contained with your medication

BEFORE YOU TAKE XENICAL (ORLISTAT)

- To benefit most from Xenical you should follow the nutrition and exercise programme recommended to you by your pharmacist, or other Healthcare professional. As with any weight-control programme, if you eat too much fat and calories your weight loss will be affected.

- This medicine can cause harmless changes in your bowel habits, such as fatty or oily stools, due to the elimination of undigested fat in your faeces. The possibility of this happening increases if Xenical is taken with a diet high in fat.

HOW TO TAKE XENICAL

- Always take Xenical exactly as your pharmacist or other Healthcare professional has instructed you. The usual dose of Xenical is one 120mg capsule taken with each of the three main meals per day. It can be taken immediately before, during a meal or up to one hour after a meal.

- Xenical should be taken with a well-balanced, calorie controlled diet that is rich in fruit and vegetables and contains not more than 30% of the calories from fat. Your pharmacist will be able to advise you on how to lower the fat in your diet.

- Try to increase your level of physical activity. Please speak to your pharmacist or the Patient Support Programme - MAP (Motivation: Advice: Proactive support) 0800 731 7138 (8am-8pm, 7 days a week) if you would like some advice.

- Your daily intake of fat, carbohydrate and protein should be spread over three meals. This means you will usually take one capsule at breakfast time, one capsule at lunch time and one capsule at dinner time.

- To gain optimal benefit, avoid the intake of food containing fat between meals, such as biscuits, chocolate and savoury snacks.

NOTE: Your pharmacist or doctor will discontinue the treatment with Xenical after 12 weeks if you have not lost at least 5% of your body weight as measured at the start of treatment with Xenical.

For further information, please read the Patient Information Leaflet provided with your medication, or contact your pharmacist.
Appendix 5: Guidance Notes for Pharmacists on Identifying Overweight Patients with Comorbidities or Obesity

Obesity is defined as a Body Mass Index (BMI) of 30kg/m² or more, where a person’s BMI is their weight in kg divided by the square of their height in metres.

\[
\text{BMI} = \frac{\text{Weight (kg)}}{\text{Height} \times \text{Height (m²)}}
\]

Overweight is defined as a BMI between 25 and 30kg/m².

Few of your customers will understand what the measurement of their BMI actually means in terms of their health, and very few are likely to know what their BMI is.

The WHO classification of obesity is described below:

<table>
<thead>
<tr>
<th>IOTF Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.5-24.9</td>
</tr>
<tr>
<td>Class I overweight</td>
<td>25-29.9</td>
</tr>
<tr>
<td>Class II Obese</td>
<td>30-34.9</td>
</tr>
<tr>
<td>Class IIa Obese</td>
<td>35-39.9</td>
</tr>
<tr>
<td>Class III Obese</td>
<td>&gt;40</td>
</tr>
</tbody>
</table>

In addition to the determination of BMI, waist circumference presents another simple way of assessing someone’s risk from overweight as fat around the waist is associated with a higher risk of developing cardiovascular and other diseases than fat in other parts of the body. Waist circumference is measured midway between the lower margin of the ribs and the top of the iliac crest laterally.

<table>
<thead>
<tr>
<th>Increased health risk</th>
<th>Substantially increased health risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men       &gt;94cm        &gt;102cm</td>
<td></td>
</tr>
<tr>
<td>Women     &gt;80cm        &gt;88cm</td>
<td></td>
</tr>
</tbody>
</table>

**Good Practice Guidance for Obesity Management**

The following investigations should be considered for patients supplied under this PGD. Responsibility for these tests should be decided locally based on expertise and facilities available within the Primary Care setting. Investigations should be carried out to:

- Isolate any medical pathology
- Act as baseline for future measurements
- Exclude any secondary conditions or co-morbidities
- Reassure patients that there is no reason why they cannot lose weight
- Ascertain that the patient has attempted long term control of weight using lifestyle measures without success
If patients are unsuccessful within the terms of this PGD, they should be referred to their GP and other treatment options considered.

It is recommended that the following investigations be carried out before the administration of orlistat:

- Height (m) and weight (kg)
- Waist circumference (cm)
- Blood pressure (mmHg)
- Urinalysis
- Blood glucose (mmol/l)
- Total cholesterol

If the patient gives the pharmacist any information, which suggests he/she may not be suitable for drug therapy for weight management, the pharmacists must not work according to the PGD, but counsel and refer the patient appropriately.

**Lifestyle and Dietary Advice (NOF Guidelines)**
http://www.nationalobesityforum.org.uk/

**Physical activity**
The aim is to achieve a 500Kcal deficit of energy requirements through:-

- changes in diet and physical activity.
- Support and encouragement e.g. through regular weight management clinics
- Targets, treatments and expectations should be agreed with patients, e.g. 0.5kg per week, or 10% maintained weight loss rather than 'ideal weight'
- Advice about co-existing risk factors e.g. alcohol, smoking, hyperlipidaemias.
- Regular follow-up appointments with initially monthly, then 1-3 monthly for at least 1 year, to help maintain weight loss.
- Permanent sustainable lifestyle changes: some activity every day; less television, computer games and sedentary lifestyles; more exercise; 30-40 minutes sustained exercise; e.g. brisk walking, swimming or cycling, at least 5 days per week.
- More exercise during daily routine; use stairs instead of lifts; walk to work, or park the car further away from work place; take a walk during lunch break. Gardening, washing the car, and activities around the home should be encouraged.
- Encourage activity as a whole family; e.g. walks or trips to the park for relaxation.

**Dietary changes**
- Establish regular meals, including breakfast & encourage healthy eating for long term weight management
- Reduce dietary fat; avoid fried food; encourage grilled, boiled or baked. Buy lean cuts of meat; avoid crisps, pies, cakes, biscuits. Use semi-skimmed milk and low fat spreads
- Encourage healthy snacks e.g. fruit as alternatives to sweets, chocolates or crisps
- Provide advice to patients about food labelling
- Encourage self-monitoring i.e. food diaries to enable patient to establish areas for change. Suggested changes need to be tailored to the individual. Giving standard diet sheets is rarely effective.
• Use locally approved advice sheets to ensure consistency of messages. Contact local dietetic departments for guidance.

Other Dietary Options

■ Meal Replacements provide a suitable option for some patients. These are structured diet plans normally involving the consumption of two meal replacement drinks per day, plus a self prepared evening meal, fruit and vegetables, totalling approximately 1200-1400kcal daily. They are purchased from supermarkets and pharmacies.

■ VLCDs (diets containing less than 800 kcals) should only be used under close medical and dietetic supervision.
Appendix 6: Wandsworth PCT Pilot Weight Management Service Protocol (draft)

Diet, exercise and counselling continue through every stage

Patient is identified and referred by Dietician  Patient identified by Community Pharmacist

- **BMI ≥ 35 with risk factors**
  - Yes: Consider GP referral

- **BMI ≥ 30 or ≥ 28 with risk factors**
  - Yes: Weight maintenance, Recalculation of goal
  - No: Second line: Consider introduction of pharmacotherapy

First line: 3-6 months on diet, exercise and counselling

- ≥ 20% weight loss
  - Yes: Weight maintenance, Recalculation of goal
  - No: No weight loss

Provide information on patient support programme

- Evidence of ≥ 2.5kg weight loss in 4 weeks
  - Yes: Prescribe orlistat 120mg tds with each main meal
    - No: Withdraw treatment

At 12 weeks check for evidence of ≥ 5% weight loss since initiation of therapy

- No: Review treatment

At 6 months check for evidence of ≥ 10% weight loss since initiation of therapy

- Yes: Review therapy at 12 months

- NO
Appendix 7 Alternative Pharmacotherapy protocol from PCT weight management guidelines

Reductil (Sibutramine)®
Prescribe Sibutramine 10mg od

Provide information on Reductil’s online weight loss plan and support program, ‘Change for life’. To access the site patients will need the personal ID number found in the starter pack and the batch number printed on the end of their Reductil pack.

www.changeforlifeonline.com

At 4 weeks* check pulse rate and BP. Check for evidence of weight loss >2kg

YES

NO

At 8 weeks* check pulse rate and BP. Evidence of weight loss >2kg in previous 4 weeks (on 15mg od)?

NO

Increase Sibutramine dose to 15mg od (if 10mg od tolerated)

Withdraw treatment & consider alternative medication

At 12 weeks* check pulse rate and BP. ≥5% since initiation of therapy?

NO

YES

At 12 weeks* check for evidence of ≥5% weight loss since initiation of therapy

Consider discontinuation after 12 months and to discontinue after 24 months

NO

After 6 months*, check pulse rate and blood pressure every 3 months. Continue therapy for up to 1 year

NO

After 3 months check pulse and BP once a month

Xenical (Orlistat)®
Prescribe Xenical 120mg tds (with each main meal)

Provide information on patient support programme (MAP Motivation, Advice, Proactive support 0800 731 7138)

www.xenicalmap.co.uk

At 12 weeks* check for evidence of ≥5% weight loss since initiation of therapy

* time since treatment started
Appendix 8: Patient Consent Form

Consent Form

For treatment by Community Pharmacist

Name and address of Pharmacy practice

Patient’s Surname

Other names

Date of Birth

Sex

PHARMACIST
(This part to be completed by Pharmacist)
Type of treatment proposed for which written evidence of consent is considered appropriate.

Complete this part of the form

I confirm that I have explained the treatment proposed and such appropriate options as are available to the patient in terms which in my judgement are suited to the understanding of the patient.

Signature

Date

Name of Pharmacist

Job Title

PATIENT

• The information provided is true and complete to the best of my knowledge.
• There is no reason to my knowledge why I cannot participate in the service.
• I understand and agree to the disclosure of my information being passed to my GP.
• I consent to my personal data and blood pressure reading being stored by the pharmacy.

I consent to the use of my anonymised data for statistical purposes.

Signature

Date

Name

Address
Appendix 9: Questioning Protocol for Supply of Orlistat under the PGD

1. Personal Details
   Pharmacy Stamp: Client's name:
   Patient reference no:
   Date of consultation:
   Age/DoB:
   Postcode:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were you referred to the pharmacy by anyone?</td>
<td>If yes, by whom?</td>
</tr>
<tr>
<td></td>
<td>• GP</td>
</tr>
<tr>
<td></td>
<td>• Other pharmacist</td>
</tr>
<tr>
<td></td>
<td>• Relative/friend</td>
</tr>
<tr>
<td></td>
<td>• Other, please specify</td>
</tr>
<tr>
<td></td>
<td>• Dietitian</td>
</tr>
<tr>
<td>Have you seen your GP about your weight, and if so, what happened?</td>
<td></td>
</tr>
</tbody>
</table>

2. Criteria for initial exclusion:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client &gt;18 years, and &lt;75 years?</td>
<td>If no, refer to GP for assessment</td>
</tr>
<tr>
<td>Is the client willing to accept treatment from a pharmacist?</td>
<td>If no, refer to GP for assessment</td>
</tr>
</tbody>
</table>

   If the client is not excluded from the PGD at this stage, the pharmacist will be eligible for a consultation fee.

3. Criteria for inclusion

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client 18-75 years?</td>
<td>If no, refer to GP</td>
</tr>
</tbody>
</table>
   | Is the patient willing to accept treatment from a pharmacist? | If no, refer to GP
   | If yes, client should sign form |
   | Is the patient registered with a GP within Wandsworth PCT? | If no, refer to relevant pharmacy or GP |
   | Does the client have a BMI>28kg/m² with at least one co-morbidity or BMI>30kg/m² | If no, consider lifestyle advice only |
   | Is there evidence of diet and exercise in the previous 3 months. | If no, provide advice on diet and exercise. Refer to dietician if necessary. Re-review client in 4 weeks |

4. Criteria for exclusion or referral

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the client have a BMI&gt;35kg/m²</td>
<td>If yes, refer to GP (Unless referred by Dietician)</td>
</tr>
<tr>
<td>Does the client have a known hypersensitivity to orlistat or its excipients?</td>
<td>If yes, refer to GP, and exclude from PGD</td>
</tr>
<tr>
<td>Does the client have current cholestasis?</td>
<td>If yes, refer to GP, and exclude from PGD</td>
</tr>
</tbody>
</table>
Appendix 9: Questioning Protocol for Supply of Orlistat under the PGD

<table>
<thead>
<tr>
<th>Question</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the client currently taking cyclosporin, acarbose, amiodarone, sibutramine or other weight loss agents?</td>
<td>If yes, client unsuitable for administration of orlistat.</td>
</tr>
<tr>
<td>Does the client suffer from chronic malabsorption syndrome?</td>
<td>If yes, refer to GP, and exclude from PGD</td>
</tr>
<tr>
<td>Is the client receiving insulin, and/or other antidiabetics?</td>
<td>If yes, the client may be at increased risk of hypoglycaemia with concurrent administration of orlistat, as weight loss can lead to improvement of glycaemic control. These patients warrant special care so that the dose of insulin can be appropriately monitored. Ensure that the clients GP agrees with the administration of orlistat.</td>
</tr>
<tr>
<td>Does the client have a blood glucose level of &gt;9mmol/l?</td>
<td>If yes/known consider informing GP if blood glucose is uncontrolled or recently detected.</td>
</tr>
<tr>
<td>Does the client have BP&gt;140/85 or 140/80 (known diabetes) on three consecutive occasions?</td>
<td>If yes/known consider informing GP if blood pressure or recently detected.</td>
</tr>
<tr>
<td>Does the client have a total cholesterol (random) of &gt;5mmol/L?</td>
<td>If yes/known consider referral to GP for advice, but accept re-referral from GP.</td>
</tr>
<tr>
<td>Has a urine test analysis tested positive for glucose, blood or protein?</td>
<td>If yes, refer to GP.</td>
</tr>
<tr>
<td>Is there any evidence of uncontrolled symptoms of other illnesses that are a cause for concern e.g. mental health, orthopaedic problems?</td>
<td>If yes, refer to GP.</td>
</tr>
</tbody>
</table>

5. Counselling

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of action discussed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side effects discussed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the client consented to their GP being informed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advice on physical activity provided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advice on diet provided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advise the patient to read the Patient Information Leaflet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advise patient to enrol with the Patient Support Programme (Medical Action Plan)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9: Questioning Protocol for Supply of Orlistat under the PGD

6. Other relevant notes:

Please record:

- Where the client heard about the scheme?

The reason for the request?

7. Action Taken

Supply: ......................................................
Batch no./expiry date: ..................................
Referral: ...................................................................................................................
.................................................................................................................................
.................................................................................................................................
.................................................................................................................................
.................................................................................................................................
................................................................................................................................. (include reasons for referral)

Advice given: ............................................................................................................
.................................................................................................................................
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.................................................................................................................................
.................................................................................................................................
.................................................................................................................................

The above information is correct to the best of my knowledge. I have been counselled on the use of orlistat and understand the advice given to me by my pharmacist. I give permission to my pharmacist to pass on this information to my GP, and the PCT for audit purposes.

Client’s signature:       Date:

The action specified was based on the information given to me by my client, which, to the best of my knowledge, is accurate.

Pharmacist’s signature:      Date:

Time taken to complete consultation: .......... mins
# APPENDIX 10; Patient Management Form page 1/2

## Patient Details
- **Name:**
- **Address:**
- **Postcode:**
- **Telephone:**
- **Date of Birth:**
- **Patient Sex:** Male, Female  
  (please tick)
- **Height:**
- **Weight:**

## General Health Information
(please tick where applicable)
- **Smoking Status:** Current Smoker, Ex-smoker, Never Smoked
- **Alcohol:** Beer pints/week, Wine glasses/week, Spirits meas/week
- **Physical Activity:** Type of activity (please specify)
  - Sessions per week:
  - Minutes per session:
- **Family History of Hypertension or coronary heart disease:** Yes, no
- **Current medical conditions:**
- **Current medication:**
- **Anti-obesity pharmacotherapy:**

## GP Details
- **Name:**
- **Address:**
- **Postcode:**
- **Telephone:**

## Declaration & Consent
- The information provided is true and complete to the best of my knowledge.
- There is no reason to my knowledge why I cannot participate in the service.
- I understand and agree to the disclosure of my information being passed to my GP.
- I consent to my personal data and blood pressure reading being stored by the pharmacy.
- I consent to the use of my anonymised data for statistical purposes.
- **Patient signature:**
- **Date:**

## Pharmacy Details
- **Name:**
- **Address:**
- **Postcode:**
- **Telephone:**
- **Pharmacist name:**

## Pharmacy Use ONLY
<table>
<thead>
<tr>
<th>Date</th>
<th>Weight (kg.)</th>
<th>BMI (kg/m²)</th>
<th>Waist (cm/ins)</th>
<th>Arm (cm/ins)</th>
</tr>
</thead>
</table>

## Advice given by pharmacist

---

39
<table>
<thead>
<tr>
<th>DATE</th>
<th>ADVICE</th>
<th>PHARMACOTHERAPY NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>SESSION 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SESSION 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Impact of Weight on Quality of Life Questionnaire—Lite Version (IWQOL-Lite)

**Client Reference number: ……………………… Date Completed: ………………………**

Please answer the following statements by circling the number that best applies to you in the past week. Be as open as possible. There are no right or wrong answers.

<table>
<thead>
<tr>
<th>Physical Function</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>8.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>9.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>10.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>11.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-esteem</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Sexual Life</td>
<td>ALWAYS TRUE</td>
<td>USUALLY TRUE</td>
<td>SOMETIMES TRUE</td>
<td>RARELY TRUE</td>
<td>NEVER TRUE</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-------------</td>
<td>--------------</td>
<td>----------------</td>
<td>-------------</td>
<td>------------</td>
</tr>
<tr>
<td>1. Because of my weight I do not enjoy sexual activity.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2. Because of my weight I have little or no sexual desire.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3. Because of my weight I have difficulty with sexual performance.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4. Because of my weight I avoid sexual encounters whenever possible.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Public Distress</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Because of my weight I experience ridicule, teasing, or unwanted attention.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2. Because of my weight I worry about fitting into seats in public places (e.g. theaters, restaurants, cars, or airplanes).</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3. Because of my weight I worry about fitting through aisles or turnstiles.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4. Because of my weight I worry about finding chairs that are strong enough to hold my weight.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5. Because of my weight I experience discrimination by others.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
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<table>
<thead>
<tr>
<th>Work (Note: For homemakers and retirees, answer with respect to your daily activities.)</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Because of my weight I have trouble getting things accomplished or meeting my responsibilities.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2. Because of my weight I am less productive than I could be.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3. Because of my weight I don’t receive appropriate raises, promotions or recognition at work.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4. Because of my weight I am afraid to go on job interviews.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix 12 Pharmacy Weight Management Clinic Patient Questionnaire

Thank you for taking part in the Pharmacy weight management clinic. We would value your feedback on how you are finding the clinic and how we could improve it. Please could you take a few minutes to complete this questionnaire and return it to the pharmacy in the envelope provided.

This service has been designed with you in mind and we are dedicated to improving it to meet your needs in order to achieve maximum success. Please be as honest as possible and feel free to add further comments about points not covered by the questions.

This questionnaire is anonymous and patient confidentiality will be maintained at all times.

1. Do you find the support and advice given by the team helpful to you in achieving your weight loss/control goals? 
   (If NO please can you explain why)
   Comments:

2. What aspects of the service were of most value to you? (circle all that apply)
   - Regular Weighing
   - Dietary advice
   - Lifestyle advice
   Comments:

4. How did you find the frequency of weighing visits? (circle choice)
   - Just right
   - Too frequent
   - Not frequent enough
   Comments:

5. If a weight management service was offered by the PCT in the future which locations would you attend? (circle all that apply)
   - Pharmacy
   - GP surgery
   - Local community centre
   Comments:

6. What didn’t you like about the service?
   Comments:

7. What did you like best about the service?
   Comments:

8. How could the service be improved?
   Comments:

Many thanks, your answers will help us develop a service to meet your needs.
Appendix 13 Invoice & audit of compliance

Practitioners should ensure that records are sufficient to audit for PGD use, this proforma has been developed to aid this process.

The Steering Group recommends annual audit of compliance with PGDs; this can either be by individual review of practice, or as part of appraisal or performance review.

For all audits, standards for compliance are 100%

Send completed form to:
[insert name of PCT, address and when the form needs to be sent in]

<table>
<thead>
<tr>
<th>Professional Fees</th>
<th>Cost of Drugs</th>
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<tbody>
<tr>
<td>Patient Ref. No.</td>
<td>Patient Ref. No.</td>
</tr>
<tr>
<td>Month</td>
<td>Date of Appointments £10/ appointment</td>
</tr>
</tbody>
</table>

Please insert the name of the pharmacy for payment to be made:

Amount claimed £_________
Appendix 14: PGD Authorised Local Community Pharmacists

The following list of pharmacists is eligible to prescribe orlistat within the local area

<table>
<thead>
<tr>
<th>Name of Pharmacist</th>
<th>Practice Address</th>
<th>Telephone no.</th>
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Appendix 15: General Practice Contact Details

The following list comprises the local GP surgeries, at which patients presenting at your pharmacy will be registered. The secure fax line should be used for informing the GP of administration of orlistat (Appendix 10).

<table>
<thead>
<tr>
<th>Name of GP</th>
<th>Practice Address</th>
<th>Secure fax no.</th>
<th>Telephone no.</th>
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</table>
Appendix 16: Dispensing Fee Charge Collection Form
(KEEP WITH PATIENT RECORDS)

Do you (the client) have to pay for this medication?

NO [ ] fill in Parts 1 and 3  YES [ ] Fill in Parts 2 and 3

Please give all details we ask for.

PART 1  For patients who do not have to pay

The patient does not have to pay because he/she:

A  Is under 16 years of age
B  Is 16, 17 or 18 and in full-time education
C  Is 60 years of age or over
D  Has a maternity exemption certificate
E  Has a medical exemption certificate
F  Has a prescription prepayment certificate
G  Has a War/MoD exemption certificate[No.]
H  * Gets Income Support
I  * Gets Family Credit
J  * Gets Disability Working Allowance
K  * Gets Income-based Jobseeker’s Allowance
L  Is named on a current HC2 charges certificate
X  Was prescribed a free-of-charge contraceptive

* Give details of person getting benefit. This may be your partner. Checks may be made with the DSS.
Name
Date of birth: / / 

PART 2  For patients who have to pay

I have paid £ [ ] for this medication ( £6.50 for one month’s supply)

Now fill in and sign Part 3

PART 3  Your declaration

I am the  [ ] patient  [ ] patient’s representative

I declare that the information is true and complete

Name (in capitals) [ ]
Address [ ] Postcode [ ]
Signed [ ] Date [ ]

WARNING: False information may lead to prosecution

Notes: Information about free prescriptions and the list of medical conditions for box E above is in leaflet HC11. You can get a copy from the pharmacy or from main Post Offices. If you think you might be entitled to free prescriptions, you must pay now and ask for an NHS receipt (form FP57). It tells you how to get your money back.
Appendix 17: Further Information

Further information on pharmacy supply under PGD can be obtained from:

Professional Standards Directorate
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London SE1 7JN
Tel: 020 7572 2308
Fax: 020 7572 2510
e-mail: profstan@rpsgb.org.uk

National Pharmaceutical Association
Mallinson House
38-42 St. Peter's Street
St. Albans
Hertfordshire AL1 3NP
Tel: 01727 832161
Fax: 01727 810252
Email: npa@npa.co.uk

Pharmaceutical Services Negotiating Committee
59 Buckingham Street
Aylesbury
Bucks HP20 2PJ
Tel: 01296 432823
Fax: 01296 392181
Email: info@psnc.org.uk

Further details on MAP can be obtained from:

Tel: 0800 731 7138
Appendix 18: Distance Learning Training Pack Orlistat
Appendix 19 Wandsworth PCT Obesity Guidelines Summary

Vision, aims and Objectives.
Appendix 20 Index of healthy eating & public health resources

1. Food standard agency
   http://www.food.gov.uk/healthiereating/

2. British Nutritional foundation
   http://www.nutrition.org.uk/home.asp?siteld=43&sectionId=s

   http://www.publications.parliament.uk/pa/cm200102/cmselect/cmpubacc/421/42103.htm

4. BBC Health eating series
   http://www.bbc.co.uk/health/healthy_living/

5. Canada’s Food Guide to Healthy Eating
   http://www.hc-sc.gc.ca/hpfb-dgpsa/onpp-bppn/food_guide_rainbow_e.html

6. Electronic Quality Information for Patients
   http://www.equip.nhs.uk/topics/promotion/nutrition.html

7. Weight Management services – Government of Victoria
Appendix 21; GP referral letter

Dear Dr

Re: Wandsworth PCT Pharmacy Weight Management Pilot

I have been selected by Wandsworth PCT to participate in the weight management service pilot programme. Over a six month period I will be guiding up to 10 selected patients through a carefully designed weight management programme.

Having undertaken the necessary training to provide this service, I will also be operating an Wandsworth PCT Orlistat PGD to enable anti obesity medication to be supplied, where appropriate and in accordance with Wandsworth PCT protocol guidelines, to be provided to further assist with a weight loss programme.

I am writing to notify you that your patient:

Name:

Has been selected for the programme and I attach the patient record/authorisation card for your records. On completion of the six month programme, a copy of the patient’s records will be sent to you. Should you, at any stage, wish access to this information, I will be happy to oblige. Data collection will include; height, weight, BMI, waist circumference and upper arm circumference. A full record of advice, pharmacotherapy and progress will also be recorded.

Please do not hesitate to contact me should you have any questions regarding this matter.

Yours faithfully
Appendix 22; GP referral & Follow up letter

Dear Dr

Re: Wandsworth PCT Pharmacy Weight Management Pilot patient name....

I would like to recommend that your patient is suitable for taking Orlistst within the Wandsworth PCT Patient group Direction Guidelines and Obesity guideline recommendations.

Please find enclosed details of your Patient’s Management Record Sheet, which is a health check as part of the weight management service.

I have noticed your patient suffers from the following: -

I would be grateful if you could confirm that you feel this patient is suitable for treatment before I commence with pharmacotherapy. I would welcome the opportunity to discuss the patient’s case with you.

Thanking you,

Yours faithfully