

ABL Orlistat guidance

Background information:

Orlistat is a lipase inhibitor which prevents the absorption of fats from the gastrointestinal and can also be used as an adjunct to lifestyle modifications for weight loss and chronic weight management.

Pharmacological treatment with orlistat will only be considered after dietary, exercise and behavioural approaches have been started and evaluated. This will involve a minimum of three months within the weight management intervention delivered within ABL Health. Drug treatment will only be considered for those:

- Meet the prescribing criteria for Orlistat.
- Who are motivated to engage with the treatment and review plan.
- Who decline/unable to follow the alternative approach.
- Failed to reach their target weight loss.
- Reached a plateau on dietary, activity and behavioural changes.

Orlistat treatment will only be started after the client completed an Orlistat information session with further discussions with the HLA. This will coincide with:

- The decision, if appropriate and mutually agreed, to request Orlistat from their GP.
- The client will be aware that the final decision about starting on Orlistat will depend on the GP.
- After discussing the potential benefits and limitations with the person, including the mode of action, adverse effects and monitoring requirements, and the potential impact on the person's motivation.

Prescribing criteria:

Only prescribe orlistat as part of an overall plan for managing obesity in adults who meet the following criteria:

- a BMI of 28 kg/m² or more with associated risk factors
- a BMI of 30 kg/m² or more

Recommended dose for orlistat is 120mg, three times a day. This should be taken immediately before, during or up to one hour after each main meal. Orlistat cost £20.39 per month. (accessed 13.8.21, this is subject to change)

Monitor the effect of drug treatment and reinforce lifestyle advice and adherence through regular review.

Continue orlistat therapy beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment. Consider withdrawing drug treatment in people who have not reached weight loss targets.

Rates of weight loss may be slower in people with type 2 diabetes, so less strict goals than those for people without diabetes may be appropriate. Agree the goals with the person and keep the GP informed of the progress.

Make the decision to use drug treatment for longer than 12 months (usually for weight maintenance) after discussing potential benefits and limitations with the person. Follow-up after 12 months will be the responsibility of the GP. The Summary of Product Characteristics (SPC) states that there are currently no data available on its use beyond 4 years.

The co-prescribing of orlistat with other drugs aimed at weight reduction is not recommended.

ABL Health will only recommend the use of orlistat to the client's GP, however the responsible GP will make the final decision on suitability of using orlistat after reviewing the client's full medical record.

Exclusion criteria:

- Pregnant or breast-feeding woman
- Under the age of 18
- Diagnosed with malabsorption syndrome like Crohn's disease, coeliac disease, or ulcerative colitis.
- A history of cholestasis (a condition where bile does not flow properly from the liver to the duodenum)
- When a patient has a clear eating disorder requiring psychotherapy
- The client is using other drugs aimed at weight reduction for instance, Saxenda (Liraglutide)
- Client with complex psychological issues will be discussed at MDT to establish their suitability to use orlistat. This will include clients with a history of an eating disorder.

Potential adverse effects:

- Abdominal distention and pain (this can be reduced by following a low-fat diet)
- Hypoglycaemia in people with Type 2 diabetes
- Influenza
- Anxiety
- Faecal incontinence and urgency with liquid, oily stools
- Flatulence and oily leakage
- Headaches and malaise
- Menstrual disturbances
- Respiratory infections
- Tooth disorders
- Urinary tract infections

*Please note that this list is not exhaustive and consider that adverse effects could be attributed to another drug.

Drug interactions and special warnings:

These medications must be highlighted to the client's GP.

- Ciclosporin (Immunosuppressant) – should not be co-prescribed with Orlistat
- Amiodarone (Irregular heartbeat)
- Antiretroviral HIV medicines
- Acarbose
- Some anti-epileptic drugs
- Warfarin (including Acenocoumarol and Phenindione)
- Anti-depressants
- Anti-psychotics – including lithium
- Benzodiazepines
- Levothyroxine
- Chronic kidney disease
- Oral contraceptive pill

*Please note that this list is not exhausted, and the prescriber should check for other drug interactions before prescribing.

Orlistat may indirectly reduce the availability of oral contraceptives through its action on the gastrointestinal tract. Woman taking the oral contraceptive pill should use an additional method of contraception, such as a condom, if they experience severe diarrhoea while taking orlistat. This is because the contraceptive pill may not be absorbed by the body if you have diarrhoea, so it may not be effective.

Orlistat may impair absorption of vitamins such as vitamin A, E, and D. Vitamin supplementation (especially of vitamin D) may be considered if there is concern about deficiency of fat-soluble vitamins. A general multivitamin should be considered in the first instance and can be purchased over the counter and should be taken at least two hours after the administration of orlistat or at bedtime, to minimise the risk of orlistat interfering with vitamin absorption.

Pathway

Orlistat will only be considered for clients who engaged in the service and their agreed treatment plan for a minimum of three months. During this time the healthy lifestyle advisor (HLA) will:

- Support the client with self-monitoring and goal setting
- Support the development of skills like using the Easy Plate model, setting SMART goals, meal planning, self-monitoring and increasing physical activity
- Alternative diet approaches have been discussed and the client declined this approach

Key discussions with clients should be focussed on:

- Stabilisation of eating
- Improving quality of the diet – Eatwell guide
- The 400-600kcal deficit approach
- Meal planning
- Shopping and food labels and special occasions
- Fat awareness and low-fat diet
- Emotional eating
- Snacking and boredom eating and alcohol
- Portion sizes
- Sleep
- Activity

After the three months of intervention, the HLA will follow the checklist below.

Checklist for suitability to use Orlistat	Yes	No
Meeting BMI criteria of: <ul style="list-style-type: none"> • a BMI of 28 kg/m² or more with associated risk factors • a BMI of 30 kg/m² or more 		
Have engaged in three months of lifestyle and dietary interventions		
Using the following medication: <ul style="list-style-type: none"> • Ciclosporin (Immunosuppressant) – should not be co-prescribed with Orlistat • Amiodarone (Irregular heartbeat) • Antiretroviral HIV medicines • Acarbose • Some anti-epileptic drugs • Warfarin (including Acenocoumarol and Phenindione) • Anti-depressants • Anti-psychotics – including lithium • Benzodiazepines • Levothyroxine • Chronic kidney disease • Oral contraceptive pill <p><i>If yes, the medication must be highlighted on the GP letter when requesting to prescribe orlistat.</i></p>		
Pregnant or breast-feeding woman		
Under the age of 18		
Diagnosed with malabsorption syndrome like Crohn's disease, coeliac disease, or ulcerative colitis.		
Diagnoses of chronic kidney disease		
A history of cholestasis (a condition where bile does not flow properly from the liver to the duodenum)		
Does the client have a diagnosis of an eating disorder		
The client is using other drugs aimed at weight reduction for instance, Saxenda (Liraglutide)		
Client with complex psychological issues will be discussed at MDT to establish their suitability to use orlistat.		
If yes to any of these, please discuss the client at MDT/ with a GP in ABL or with the specialist dietitian in ABL.		
If yes to any of these, please discuss the client at MDT/ with a GP in ABL or with the specialist dietitian in ABL.		

If the client meets the criteria, the HLA will book the client onto the Orlistat Information session. This session will include a handbook to support the client further and encourage self-monitoring and problem solving. This Orlistat Information session will be delivered monthly and will include the following topics:

- How Orlistat works and how to take this to give maximum benefits
- The benefits and risks of using Orlistat
- Possible drug interactions, cautions and multi-vitamin supplementation
- Expectations of weight loss and engagement with the service while using orlistat
- How Orlistat should be used
- Side-effects of Orlistat
- Dietary guidance: low fat diet, portion control, easy plate
- Dietary changes needed to avoid side-effects
- Improving physical activity and portion control
- Using self-monitoring to aid weight loss
- Problem solving
- Strategies to maintain weight when orlistat is stopped

Nutritional advice summary

- Recommend a low fat (30%) diet, e.g., 22g of fat per meal (based on a diet of 2000 calories and 3 meals per day)
- Take Orlistat with meals (immediately before, during or up to 1 hour after a meal)
- Distribute fat from the diet evenly over the 3 main meals
- Avoid fatty foods in between meals, e.g., cakes, biscuits, crisps
- DO NOT take Orlistat if a meal is missed or does not contain fat

On completion of the Orlistat information session:

- HLA to contact the client to establish if they wish to continue this treatment plan.
- Decline orlistat – discuss alternative offers i.e., conservative weight management, alternative diet approaches. Continue support in the service.
- Accept orlistat – HLA to assess the client's:
 - Weight and BMI to calculate 5% weight loss goal
 - Understanding of the pros and cons of using Orlistat
 - Understanding of a low-fat diet and recommend starting on a low-fat diet before starting on Orlistat.
 - Understanding of the expected weight loss and their individual 5% weight loss target they need to achieve in 3 months.
 - Understanding that their GP will have to review their medical record to ensure they are suitable to use Orlistat – The GP will have the final decision.
 - Withdrawal of orlistat should they:
 - Not achieve 5% weight loss in the first 3 months
 - Gain weight at any stage whilst using Orlistat
 - Disengage with the service or decline further input
 - Unable to tolerate Orlistat

- The HLA will give the client a letter to take to their own GP (Appendix 1) and send out a copy of the letter to the GP to request a prescription for Orlistat for three months (Appendix 2).
- Client must inform the HLA of the date they started on Orlistat. The HLA will record this on the database and:
 - Add a note “Management on Orlistat” on the client’s ABL record in the information box on the client information panel.
 - Update the client’s medication list by adding Orlistat to this list. (This will allow ABL to audit the usage and outcomes).
- The HLA will book a monthly follow-up with the client and report back to the GP after three months. (Appendix 3). A progress report will be completed and send to the GP at 6 and 9 months after the first 3 months have been completed. HLA to set a call back on the database at these touch points.
- Withdrawing orlistat: (See Appendix 3 for letter back to the GP)
 - 5% weight loss not reached. Less strict goals may be considered for those with Type 2 diabetes, and this should be discussed at MDT and with the GP.
 - Weight gain during any stage of the treatment plan
 - Client feels unable to cope with the side-effects
 - Failing to engage/attend appointments leading to a discharge or self-discharge

Note: If withdrawing orlistat, an alternative must be offered to support the client.

- Orlistat can be continued post 12 months but will need a review with the GP before this is recommended. ABL will have monthly contact with a client post 12-month intervention until a discharge has been mutually agreed.

Appendices

Appendix 1

Standard letter to client to discuss orlistat with their GP

Dear [clients name](#),

Thank you for attending the Orlistat information session. I hope you found the session useful. The handbook should help to keep you on track and to avoid any unwanted side-effects from eating too much fat.

Please remember that Orlistat is only a tool to help you to modify or reduce the amounts of fats you eat. Clients who did very well with weight loss while on Orlistat, worked hard to make dietary and lifestyle changes and they continued with these changes after Orlistat was stopped.

Orlistat should be taken three times a day with your meals. Do not take Orlistat if you skipped a meal. However, skipping meals could lead to snacking or overeating at the next meal, so this is not advisable.

As discussed, your GP will make the final decision if you are suitable to use Orlistat. They will need to look at your past medical history to make sure it is safe for you to use Orlistat.

Action Needed:

- Please make an appointment with your GP, clinical pharmacist, or prescribing practice nurse to discuss this further. Please note that I have send out a letter to your GP but would recommend you take this letter and your handbook with you should you wish to discuss this further with your GP, clinical pharmacist, or practice nurse.
- Let your HLA know what date you start taking Orlistat to help us keep track of the length of time you are using it.
- Continue to attend all your appointments with the team. Failure to do so means we are unable to monitor your progress and the Orlistat prescription will be discontinued.

Feel free to contact us if you need further information.

Kind regards,

Healthy Lifestyle Advisor

Twané Celliers
Specialist dietitian

Appendix 2

Letter to GP to request a review of the clients records to assess suitability for orlistat and prescribe if appropriate.

Dear GP.

Client name, DOB, address, NHS number

Thank you for referring **client name** to the **Choose to Change / Your Health Oldham** weight management service. We have been working with **client name** since **date**. **Client name** wish to trial Orlistat to enhance their weight loss efforts and have followed the ABL Choose to Change Orlistat pathway which is in line with the NICE recommendations.

They attended the Orlistat Information session which covered the following topics:

- How Orlistat works and how to take this to give maximum benefits
- The benefits and risks of using Orlistat
- Possible drug interactions, cautions and multi-vitamin supplementation
- Expectations of weight loss and engagement with the service while using orlistat
- How Orlistat should be used
- Side-effects of Orlistat
- Dietary guidance: low fat diet, portion control, easy plate
- Dietary changes needed to avoid side-effects
- Improving physical activity and portion control
- Using self-monitoring to aid weight loss
- Problem solving
- Strategies to maintain weight when orlistat is stopped

Client name understands that you will need to assess their records to ensure they are safe to use Orlistat. We have asked them to make an appointment to discuss this further. **Client name** is aware that you will have the final decision about their suitability to use Orlistat.

Please note that we, as providers, don't have access to the clients full medical records and will rely on you expert opinion when deciding if this is a suitable drug for your patient.

Action needed:

- We would appreciate it if you could prescribe Orlistat at 120mg TDS for the next 3 months.

We have asked **client name** to contact you directly should they experience symptoms of headaches, malaise, menstrual disturbances, respiratory infections, tooth disorder or urinary tract infection as this may lead to a withdrawal of Orlistat.

We will continue to support **client name** monthly and will report back to you on their progress after three months or sooner if there are any reasons to withdraw orlistat before then.

Please feel free to contact us if you need further information.

Kind regards,

Healthy Lifestyle Advisor

Twané Celliers
Specialist Dietitian

Copy to:

Client

Appendix 3

Report back to GP to continue orlistat prescription as 5% weight loss was achieved, or client has a diabetes, and we recommend continuing with orlistat OR withdrawal of Orlistat.

Dear GP,

Orlistat Report

Client name, DOB, address, NHS number

We continue to support *client name* while they are using orlistat and working towards achieving a healthier weight. Thank you for prescribing this for 3 months.

They started using orlistat on *Date*

Starting weight and BMI		Current weight and BMI	
Weight (kg)	BMI (kg/m ²)	Weight (kg)	BMI (kg/m ²)

(HLA to choose the correct option and delete the rest)

1. Achieved 5% weight loss

Client name has achieved a 5% weight loss and wishes to continue using orlistat to support their weight loss. We would recommend a further 9 months of Orlistat prescriptions to help lower or maintain weight loss. We will keep you informed of the progress at 6 and 9 months and we will let you know if Orlistat needs withdrawing if the client gain weight or disengage with the service.

2. Diabetes client that achieved weight loss but not 5%

Client name has not achieved 5% of weight loss but have done well by achieving x % weight loss so far. NICE recommends that for people with diabetes, less strict targets should be considered due to benefit of losing weight on reducing the risk factors associated with diabetes. We would recommend a further 9 months of Orlistat prescriptions to help lower or maintain weight loss. We will keep you informed of the progress at 6 and 9 months and we will let you know if Orlistat needs withdrawing if the client gain weight or disengage with the service.

3. Did not achieve 5% weight loss

Unfortunately, *client name*, did not achieve the recommended 5% weight loss as recommended by the NICE guidance. We would recommend withdrawing the prescription. *Client name* is aware that we would be making this recommendation. We will continue to support *client name* in the weight loss service.

4. Client unable to tolerate orlistat

Unfortunately, client name is unable to tolerate orlistat and therefore we would recommend withdrawing the prescriptions.

5. Client disengage/self-discharge

Unfortunately, **client name** is no longer taking part in the weight management service. We are unable to monitor their progress on orlistat and for this reason we would recommend that you withdraw the orlistat prescriptions. Please feel free to refer the client back to our service when appropriate.

Please feel free to contact us if you need further information.

Yours sincerely,

Healthy lifestyle advisor

Twané Celliers
Specialist Dietitian

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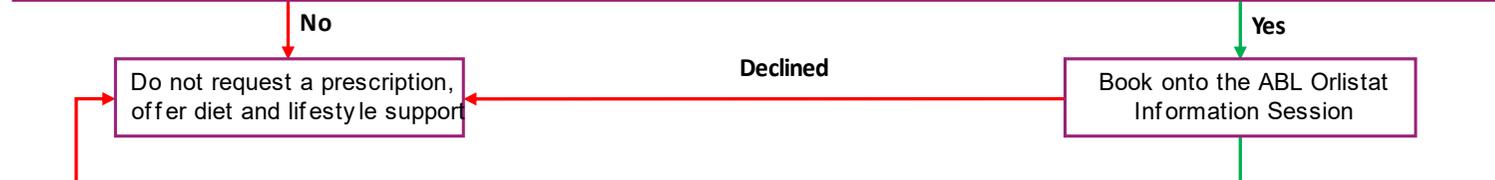
The client

References:

1. National Institute for Health and Care Excellence (NICE),
<https://cks.nice.org.uk/topics/obesity/prescribing-information/orlistat/> [Accessed in August 2021]
2. (CG189) (2014) Obesity: identification, assessment, and management. London.
<https://www.nice.org.uk/guidance/cg189> [Accessed in July 2021]
3. British National Formulary (BNF) (2020) BNF,
<https://bnf.nice.org.uk/drug/orlistat.html> [Accessed in July 2021]
4. Summary of Product Characteristics for Xenical (orlistat).
<https://www.medicines.org.uk/emc/product/2592/smpc> [Accessed July 2021]

Guidance for Prescribing and Reviewing Orlistat in ABL Health

Starting Prescription: Does the client meet the prescribing criteria?
 > 3 months diet and lifestyle intervention
 Meet criteria - BMI >30kg/m² OR BMI >28kg/m² AND comorbidities, e.g., Diabetes, hypertension, or sleep apnoea



- Nutritional Advice:**
- Low fat diet (30% or 22g of fat per meal, based on 2000 calories & 3 meals per day).
 - Take Orlistat immediately before, during, or up to 1 hour after a meal.
 - Distribute fat from diet evenly over the 3 main meals. Avoid fatty foods in between meals, e.g., cakes, biscuits, crisps.
 - DO NOT take Orlistat if a meal is missed or contains no fat.

- Key worker Assessment:**
- Provide letter (A1) to client and a mail copy to GP to request an orlistat prescription at 120mg TDS, for 3 months.
 - GP to make final decision on suitability.
 - Continue to review monthly as part of the treatment plan – diet, lifestyle, and behavioural approaches

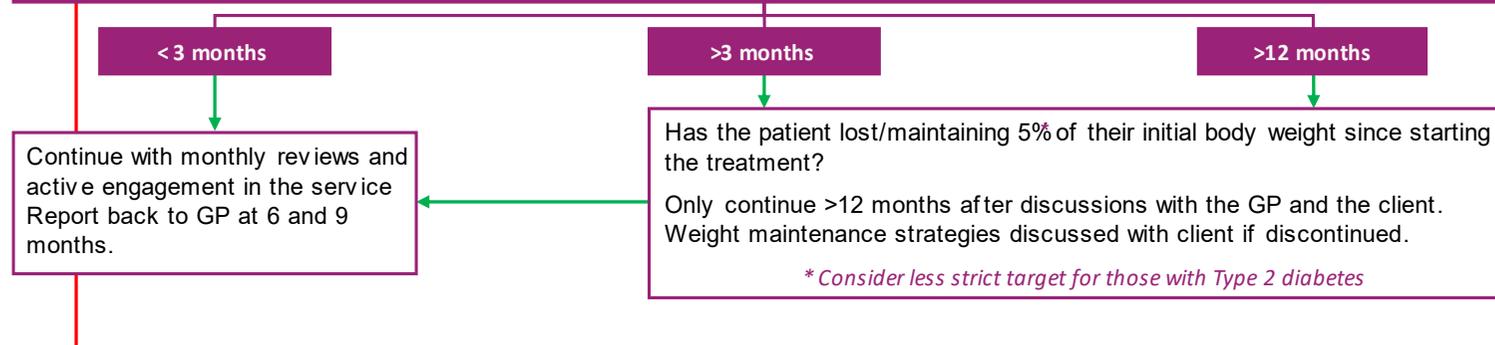
Main Side Effects:

Abdominal distension /pain (effects minimised by reduced fat intake); faecal incontinence /urgency; flatulence; hypoglycaemia; liquid stools; oily leakage from rectum; oily stools.

Contraindications/Cautions:

Breastfeeding, pregnancy, cholestasis & chronic malabsorption syndrome
 Potential Drug Interactions
 Acarbose®, Anticoagulants, Ciclosporin®, Iodine salts, Levodopa®, Amiodarone®, antiretroviral, antiepileptic. [BNF link](#)

Reviewing prescriptions and progress:
 How long has the client been on orlistat?



- Discontinue treatment (A2):**
- < 5%* weight loss after 3 months - offer alternative support.
 - Weight gain.
 - Failing to engage/self discharge.
 - Client feels unable to cope with the side-effects.