# Clinical Policy: Weight Loss

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Line of Business: Arizona Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

The following are for weight loss requiring prior authorization: phentermine (Adipex-P®, Lomaira™), orlistat (Alli®, Xenical®), lorcaserin hydrochloride (Belviq®, Belviq XR®), bupropion SR/naltrexone SR (Contrave®), methamphetamine (Desoxyn®), benzphetamine hydrochloride (Didrex®, Regimex™), , phentermine and topiramate extended release (Qsymia®), liraglutide (Saxenda®), diethylpropion hydrochloride (Tenuate®, Tenuate Dospan®).

## FDA approved indication

- Xenical is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss.
- Phentermine (Adipex-P, Lomaira,) is indicated as a short term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index (BMI) ≥ 30 kg/m$^2$ or ≥ 27 kg/m$^2$ in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).
- Desoxyn is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.
- Desoxyn is indicated as a short-term (i.e., a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs.
- Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese) or 27 kg/m$^2$ or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.
- Belviq/Belviq XR is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult with an initial body mass index (BMI) of:
    - ≥ 30 kg/m$^2$ (obese) OR

    - ≥ 27 kg/m$^2$ (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)
- Alli is an over-the-counter product indicated for weight loss in overweight adults 18 years and older, when used along with a reduced-calorie and low-fat diet.
- Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m$^2$ or greater (obese) or 27 kg/m$^2$ or greater (overweight) in the presence of at least one weight related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).
- Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial BMI of 30 kg/m$^2$ or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.
- Benzphetamine (Didrex, Regimex) is indicated in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in patients with an initial BMI of 30 kg/m$^2$ or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.
- Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m$^2$ or greater (obese) or 27 kg/m$^2$ or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

Limitation of use:

- The safety and efficacy of co-administering Belviq, Belviq XR, Contrave or Qsymia with other products intended for weight loss including prescription drugs (e.g., phentermine), over the counter drugs, herbal preparations have not been established.
- The effects of Belviq, Belviq XR, Contrave, Qsymia or Saxenda on cardiovascular morbidity and mortality have not been established.
- Saxenda is not indicated for the treatment of type 2 diabetes mellitus.
- Saxenda and Victoza® both contain the same active ingredient, liraglutide, and therefore should not be used together. Saxenda should not be used in combination with any other GLP-1 receptor agonist.
- Saxenda has not been studied in patients taking insulin. Saxenda and insulin should not be used together.
- Saxenda has not been studied in patients with a history of pancreatitis.

**Policy/Criteria**

*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation® that Adipex-P, Alli, Belviq, Belviq XR, Contrave, Desoxyn, Didrex, Lomaira, Qsymia, Regimex, Saxenda, Tenuate, Tenuate Dospan, and Xenical are **medically necessary** when the following criteria are met:

## I. Initial Approval Criteria

### A. Exogenous Obesity (must meet all):

1. One of the following (a or b):
   a. Body Mass Index (BMI) is ≥ 30 kg/m$^2$;
   b. Body Mass Index (BMI) is ≥ 27 kg/m$^2$ with one or more of the following weight related conditions such as:
      i. Coronary artery/heart disease:
      ii. Diabetes
      iii. Dyslipidemia
      iv. Hypertension
      v. Obstructive sleep apnea
2. For Adipex-P, Lomaira, Tenuate, Tenuate Dospan, age >16;
3. For Alli, Belviq, Belviq XR, Contrave, Qsymia, Saxenda, age ≥18;
4. For Xenical, Desoxyn, benzphetamine, age ≥12;
5. Documentation of the patient's baseline weight is required to determine response to therapy;
6. Documentation of participation in a physician-supervised diet, exercise and behavior modification program for at least six months
7. For phentermine and methamphetamine requests only: Failure to a trial of Xenical (at up to maximally indicated dose) unless contraindicated or clinically significant adverse effects are experienced.
8. Dose does not exceed the following:
   a. Alli: 180 mg/day;
   b. Adipex-P: 37.5 mg/day;
   c. Belviq/Belviq XR: 20 mg/day;
   d. Contrave: 32/360 mg/day;
   e. Desoxyn: 15 mg/day;
   f. Didrex, Regimex: 150 mg/day;
   g. Lomaira: 24 mg/day;
   h. Qsymia: 15 mg/92 mg/day;
   i. Saxenda: 3 mg/day;
   j. Tenuate, Tenuate Dospan: 75 mg/day;
   k. Xenical: 360 mg/day.

**Approval duration:**

- **Alli, Xenical: 6 months**
- **Contrave, Saxenda: 16 weeks**
- **Belviq, Belviq XR, Didrex, Lomaira, Qsymia, Regimex, Tenuate, Tenuate Dospan: 12 weeks**
- **Desoxyn: 4 weeks**

### B. Attention Deficit Hyperactivity Disorder (ADHD)

1. Diagnosis of ADHD;
2. Request is for methamphetamine;
3. Dose does not exceed 25 mg/day.

**Approval duration: Length of Benefit**

**C. Other diagnoses/indications**

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## II. Continued Therapy

**A. Exogenous Obesity** (must meet all)

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. For Qsymia requests:
   a. First reauthorization: Documentation of a 3% weight loss after 12 weeks on 7.5 mg/46 mg, unless request is for a dose escalation;
   b. Second reauthorization: Documentation of at least 5% weight loss from baseline body weight and continuation in a formalized weight management program;
   c. Reauthorizations beyond the first year: Documentation of weight maintenance and continuation in a formalized weight management program;
3. For Contrave requests:
   a. First reauthorization: Documentation of a >5% weight loss after 16 weeks of therapy;
   b. Subsequent reauthorizations: Documentation of weight maintenance and continuation in a formalized weight management program;
4. For Xenical requests:
   a. First reauthorization: Documentation of a 5% weight loss during the previous 6 month period and continuation in a formalized weight management program;
   b. Subsequent reauthorizations: Documentation of weight maintenance and continuation in a formalized weight management program;
5. For Alli requests:
   a. First reauthorization: Documentation of a 5-10 pound weight loss during the previous 6 month period and continuation in a formalized weight management program;
   b. Subsequent reauthorizations: Documentation of weight maintenance and continuation in a formalized weight management program;
6. For Belviq and Belviq XR requests:
   a. First reauthorization: Documentation of a >5% weight loss after 12 weeks of therapy and continuation in a formalized weight management program;
   b. Subsequent reauthorizations: Documentation of weight maintenance and continuation in a formalized weight management program;
7. For Saxenda requests:
   a. First reauthorization: Documentation of at least a 4% weight loss after 16 weeks of therapy;
   b. Subsequent reauthorizations: Documentation of weight maintenance and continuation in a formalized weight management program;
8. For Desoxyn requests, documentation of weight reduction and continuation in a formalized weight management program;
9. If request is for a dose increase, new dose does not exceed the following:
   a. Alli: 180 mg/day;
   b. Adipex-P: 37.5 mg/day;

c. Belviq/Belviq XR: 20 mg/day;
d. Contrave: 32/360 mg/day;
e. Desoxyn: 5 mg before each meal;
f. Didrex, Regimex: 150 mg/day;
g. Lomaira: 24 mg/day;
h. Qsymia: 15 mg/92 mg/day;
i. Saxenda: 3 mg/day;
j. Tenuate, Tenuate Dospan: 75 mg/day;
k. Xenical: 360 mg/day.

**Approval duration:**

- **Adipex-P, Lomaira, Tenuate, Tenuate Dospan, Didrex, Regimex: up to 3 months total**
- **Desoxyn: 3 months**
- **For all others:**
  - **First reauthorizations:**
    - **Alli, Xenical: 6 months**
    - **Belviq, Belviq XR, Qsymia, Contrave: 12 weeks**
    - **Saxenda: 36 weeks**
  - **Subsequent reauthorizations 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
BMI: Body mass index
MTC: Medullary thyroid carcinoma
MEN 2: Multiple Endocrine Neoplasia syndrome type 2

*Appendix B: General Information*

- BMI = 703 x [Weight (lbs)/Height (inches)2]
- Examples of coronary artery/heart disease include: Coronary Artery Bypass Graft, angina, history of myocardial infarction or stroke.
- Contrave has increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.
- Saxenda should be monitored for depression or suicidal thoughts. Discontinue if symptoms develop.

- Saxenda is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Pediatric Use
  - Phentermine, Tenuate, Tenuate Dospan – Safety and effectiveness in pediatric patients less than or equal to 16 years of age have not been established. The use of this product to treat pediatric obesity is not recommended.
  - Belviq, Belviq XR, Contrave, Qsymia or Saxenda – Safety and effectiveness in pediatric patients below the age of 18 have not been established and the use is not recommended in pediatric patients.
  - Xenical – Safety and effectiveness in pediatric patients below the age of 12 have not been established.
  - Desoxyn, benzphetamine – Safety and effectiveness in pediatric patients below the age of 12 have not been established.
- Qsymia is only available through certified pharmacies that are enrolled in the Qsymia certified pharmacy network. Additional information may be obtained via the website www.QsymiaREMS.com or by telephone at 1-888-998-4887.

*Appendix C: Therapeutic Alternatives*
N/A

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Alli | 60 mg PO TID with each main meal containing fat | 180 mg/day |
| Belviq | 10 mg PO BID | 20 mg/day |
| Belviq XR | 20 mg PO QD | 20 mg/day |
| Contrave | 8/90 mg PO QAM for one week, then 8/90 mg PO BID for one week; increase dose weekly by one tablet per day until the maintenance dose of two 8/90 mg tablets PO BID is reached (week 4). | 32 mg/360 mg |
| Desoxyn | Exogenous obesity:<br>For patients ≥ 12 yo: 5 mg PO 30 minutes before each meal. | 15 mg/day |
| | ADHD:<br>For patients 6 years or older, an initial dose of 5 mg PO QD or BID. Daily dosage may be raised in increments of 5 mg at | 25 mg/day |

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|---|---|---|
| | weekly intervals.<br>The usual effective dose is 20-25 mg daily. The total daily dose may be given in two divided doses. | |
| Didrex, Regimex | 25-50 mg PO QD-TID | 150 mg/day |
| Lomaira | 8 mg PO TID ½ hour before meals | 24 mg/day |
| Phentermine (Adipex-P) | 37.5 mg PO QD before breakfast or 1 to 2 hours after breakfast | 37.5 mg/day |
| Qsymia | 3.75 mg/23 mg PO QD for 14 days; then increase to 7.5 mg/46 mg PO QD.<br><br>If patient has not lost at least 3% of baseline body weight on 7.5 mg/46 mg, discontinue or escalate the dose.<br><br>To escalate the dose, increase to 11.25 mg/69 mg PO QD for 14 days, followed by 15 mg/92 mg PO QD<br><br>Note that 3.75 mg/23 mg and 11.25 mg/69 mg are for titration purposes only.<br><br>Discontinue 15 mg/92 mg dose gradually by taking a dose every other day for at least 1 week prior to stopping treatment altogether, due to the possibility of precipitating a seizure. | 15 mg/92 mg |
| Saxenda | 3 mg SC QD<br>Start with 0.6mg QD for 1 week and increase by 0.6mg increments per week until 3mg QD is reached. | 3 mg/day |
| Tenuate | 25 mg IR tablet PO TID, 1 hour before meals | 75 mg/day |

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|---|---|---|
| Tenuate Dospan | 75 mg CR tablet PO QD mid-morning | 75 mg/day |
| Xenical | 120 mg PO TID with each main meal containing fat | 360 mg/day |
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## VI. Product Availability

| Drug | Availability |
|---|---|
| Adipex-P | Capsule and Tablet: 37.5 mg |
| Alli | Capsule: 60 mg |
| Belviq | Tablet: 10 mg |
| Belviq XR | Tablet: 20 mg extended-release |
| Contrave | Tablet: 8 mg naltrexone/90 mg bupropion extended-release |
| Desoxyn | Tablet: 5 mg |
| Didrex | Tablet: 50 mg |
| Lomaira | Tablet: 5 mg |
| Phentermine | Tablet: 37.5 mg |
| | Capsule: 15 mg, 30 mg, 37.5 mg |
| Qsymia | Capsule: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg |
| Regimex | Tablet: 25 mg |
| Saxenda | Pre-filled Pen: 6mg/mL, 3mL, multi-dose pens in a box of 5 pens |
| Tenuate | Tablet: 25 mg immediate-release (IR) |
| Tenuate Dospan | Tablet: 75 mg controlled-release (CR) |
| Xenical | Capsule: 120 mg |

## VII. References

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5. Desoxyn [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; May 2017.
6. Contrave [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
7. Alli [Drug Facts] Moon Township, PA: GlaxoSmithKline, May 2016.
8. Saxenda [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; May 2017.
9. Tenuate, Tenuate Dospan [Prescribing Information] Bridgewater, NJ: Merrell Pharmaceuticals Inc.; November 2003.
10. Didrex [Prescribing Information]. New York, NY: Pfizer; December 2016.

11. Regimex [Package Insert]. Atlanta, GA: Mikart, Inc.; March 2013.
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13. National Heart, Lung, and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The Evidence Report. NIH Publication No. 98-4083. 1998.
14. Torgerson JS, Hauptman J, Boldrin MN, et al. Xenical in the prevention of diabetes in obese subjects (XENDOS) study: a randomized study of orlistat as an adjunct to lifestyle changes for the prevention of type 2 diabetes in obese patients. *Diabetes Care* 2004;27:155-161.
15. Lomaira [Prescribing Information] Newton, PA: KVK-Tech Inc.; September 2016.
16. Belviq XR [Prescribing Information] Woodcliff Lake, NJ: Eisai Inc,; May 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Converted to new template<br>Annual Review – Removed Suprenza (no longer on market) | 06.17 | 11.17 |
| Annual Review – Updated references | 09.11.18 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.