Clinical Policy: Weight Loss Medications

Reference Number: AZ.CP.PMN.1004
Effective Date: 11.16.16
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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: benzphetamine (Didrex®, Regimex®), bupropion SR/naltrexone SR (Contrave®), diethylpropion hydrochloride (Tenuate®, Tenuate Dospan®), liraglutide (Saxenda®), lorcaserin hydrochloride (Belviq®, Belviq XR®), orlistat (Xenical®), phendimetrazine (Bontril SR®, Bontril PDM®), phentermine (Adipex-P®, Lomaira™), and phentermine and topiramate extended release (Qsymia®).

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).
- 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)
- 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).
- Diethylpropion (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 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 Arizona Complete Health that Adipex-P, Bonstril SR, Bonstril PDM, Belviq, Belviq XR, Contrave, 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 phentermine, or diethylpropion, age >16;
3. For phendimetrazine, Belviq, Belviq XR, Contrave, Qsymia, or Saxenda, age ≥18;

4. For benzphetamine or Xenical age ≥12;
5. Documentation of the patient's baseline weight is required to determine response to therapy;
6. Documentation of participation in a physician/dietician-supervised (nutrition-balanced and reduced-calorie) diet, exercise and behavior modification programs for at least six months;
7. For benzphetamine, diethylpropion, phentermine, and phendimetrazine requests only: Failure to a trial of Xenical (at up to maximally indicated dose) unless contraindicated or clinically significant adverse effects are experienced;
8. Females of reproductive age: negative pregnancy test;
9. Member does not have contraindications to the requested drug (*see Appendix C*);
10. Dose does not exceed the following:
    a. Belviq/Belviq XR: 20 mg/day;
    b. Benzphetamine: 150 mg/day;
    c. Contrave: 32/360 mg/day;
    d. Diethylpropion: 75 mg/day;
    e. Lomaira: 24 mg/day;
    f. Phentermine (other than Lomaira): 37.5 mg/day;
    g. Phendimetrazine: 105 mg/day (extended-release), 210 mg/day (immediate-release)
    h. Qsymia: 15 mg/92 mg/day;
    i. Saxenda: 3 mg/day;
    j. Xenical: 360 mg/day.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to AZ.CP.PMN.53 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 reauthorizations beyond initial 12 weeks of approval (must meet all):
    a. Request is for Belviq/Belviq XR, Contrave, Qsymia, Saxenda, or Xenical;
    b. Females of reproductive age: negative pregnancy test;
    c. Member does not have contraindications to the requested drug (*see Appendix C*);
    d. Documentation that member is continuing in a formalized weight management program;
    e. Member has lost at least 5% of baseline body weight after 12 weeks of tolerated maximum-dose therapy, and has a BMI ≥ 25;
3. If request is for a dose increase, new dose does not exceed the following:
    a. Belviq/Belviq XR: 20 mg/day;
    b. Benzphetamine: 150 mg/day;
    c. Contrave: 32/360 mg/day;
    d. Diethylpropion: 75 mg/day;

e. Lomaira: 24 mg/day;
f. Phentermine (other than Lomaira): 37.5 mg/day;
g. Phendimetrazine: 105 mg/day (extended-release), 210 mg/day (immediate-release)
h. Qsymia: 15 mg/92 mg/day;
i. Saxenda: 3 mg/day;
j. Xenical: 360 mg/day.

Approval duration:

- **Benzphetamine, diethylpropion, phendimetrazine, and phentermine: up to 3 months total**
- **For all others: 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 6 months (whichever is less); or
2. Refer to AZ.CP.PMN.53 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 – AZ.CP.PMN.53 for Arizona Medicaid

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: Therapeutic Alternatives
N/A

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious hypersensitivity reaction to the requested drug product
  - Pregnancy
  - Xenical:
    - Cholestasis
    - Chronic malabsorption syndrome
  - Contrave:
    - Seizure disorder or past history of seizures
    - Concomitant use of bupropion or bupropion-containing products
    - Concomitant use of chronic opioids, opiate agonists (eg, methadone), or partial agonists (eg, buprenorphine)

        - Concomitant use of an MAOI, including linezolid or IV methylene blue, or use within 14 days of MAOI discontinuation
        - Uncontrolled hypertension
    - Benzphetamine, diethylpropion, phentermine, and phendimetrazine:
        - Agitated states
        - Cardiovascular disease, history of, including uncontrolled hypertension, stroke, coronary artery disease, arrhythmias, and congestive heart failure
        - Concomitant use with MAOIs; at least 14 days should elapse between use of phentermine and an MAOI
        - History of drug abuse
        - Glaucoma
        - Hyperthyroidism
        - Nursing or lactating women
    - Saxenda:
        - Personal or family history of medullary thyroid carcinoma
        - Personal of family history of multiple endocrine neoplasia syndrome type 2
    - Qsymia:
        - Concomitant use with MAOI therapy or within 14 days of discontinuation of MAOI
        - Glaucoma
        - Hyperthyroidism
- Boxed warning(s):
    - Contrave:
        - Naltrexone hydrochloride/buPROPion hydrochloride is not approved for use in the treatment of major depressant disorder or other psychiatric disorders
    - Saxenda:
        - Thyroid C-cell tumors

Appendix D: 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.
- 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.

- 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.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Belviq	10 mg PO BID	20 mg/day
Belviq XR	20 mg PO QD	20 mg/day
Contrave	8 mg/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 mg/90 mg tablets PO BID is reached (week 4).	32 mg/360 mg
Benzphetamine (Didrex, Regimex)	25-50 mg PO QD-TID	150 mg/day
Phentermine (Lomaira)	8 mg PO TID ½ hour before meals	24 mg/day
Phentermine (Adipex-P)	15 - 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. If patient has not lost at least 3% of baseline body weight on 7.5 mg/46 mg, discontinue or escalate the dose. To escalate the dose, increase to 11.25 mg/69 mg PO QD for 14 days, followed by 15 mg/92 mg PO QD Note that 3.75 mg/23 mg and 11.25 mg/69 mg are for titration purposes only.	15 mg/92 mg

	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.	
Saxenda	3 mg SC QD Start with 0.6mg QD for 1 week and increase by 0.6 mg increments per week until 3mg QD is reached.	3 mg/day
Diethylpropion (Tenuate)	25 mg IR tablet PO TID, 1 hour before meals	75 mg/day
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
Phendimetrazine (Bontril SR, Bontril PDM)	35 mg IR tablet PO BID – TID, 1 hour before meals 105 mg ER capsule PO QD, 30 to 60 minutes before breakfast	IR: 210 mg/day ER: 105 mg/day

VI. Product Availability

Drug	Availability
Belviq	Tablet: 10 mg
Belviq XR	Tablet: 20 mg extended-release
Contrave	Tablet: 8 mg naltrexone/90 mg bupropion extended-release
Benzphetamine (Didrex, Regimex)	Tablet: 25 mg, 50 mg
Phentermine (Lomaira)	Tablet: 8 mg
Phentermine (Apidex-P)	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
Saxenda	Pre-filled Pen: 6mg/mL, 3mL, multi-dose pens in a box of 5 pens
Diethylpropion (Tenuate)	Tablet: 25 mg immediate-release (IR)
Diethylpropion (Tenuate Dospan)	Tablet: 75 mg controlled-release (CR)
Xenical	Capsule: 120 mg
Phendimetrazine (Bontril SR, Bontril PDM)	Tablet: 35 mg immediate-release (IR) Capsule: 105 mg extended-release (ER)

VII. References

1. Adipex-P [Prescribing Information] Sellersville, PA: TevaPharmaceuticals; July 2014.
2. Belviq [Prescribing Information] Zofingen, Switzerland: Arena Pharmaceuticals GmbH; May 2017.
3. Belviq XR [Prescribing Information] Woodcliff Lake, NJ: Eisai Inc,; May 2017.
4. Contrave [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
5. Didrex [Prescribing Information]. New York, NY: Pfizer; December 2016.
6. Lomaira [Prescribing Information] Newton, PA: KVK-Tech Inc.; September 2016.
7. Phendimetrazine [Prescribing Information] Princeton, NJ: Sandoz Inc.; October 2011.
8. Qsymia [package insert]. Mountain View, CA: Vivus Inc; March 2018.
9. Regimex [Package Insert]. Atlanta, GA: Mikart, Inc.; March 2013.
10. Saxenda [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; March 2020.
11. Tenuate, Tenuate Dospan [Prescribing Information] Bridgewater, NJ: Merrell Pharmaceuticals Inc.; November 2003.
12. Xenical [Prescribing Information] South San Francisco, CA: Genentech USA, Inc.; August 2015.
13. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 2017.
14. 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.
15. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Annual Review – Removed Suprenza (no longer on market)	06.17	11.17
Annual Review – Updated references	09.11.18	09.18
Annual Review – added phendimetrazine; removed Alli; added a criterion for females of reproductive age: negative pregnancy test, Member does not have contraindications to the requested drug; revised initial approval duration: 3 months; revised continued therapy approval duration: 3 months total for Noradrenergic Sympathomimetic Drugs (Benzphetamine, Phendimetrazine, Phentermine, Diethylpropion), 6 months for all other drugs; revised continued therapy approval criteria: Member has lost at least 5% of baseline body weight after 12 weeks of tolerated maximum-dose therapy, and has a BMI ≥ 25 for	08.26.19	01.2020

Reviews, Revisions, and Approvals	Date	P&T Approval Date
all drugs; removed methamphetamine (Desoxyn); updated references; Renumbered from AZ.CP.PHAR.198 to AZ.CP.PMN.1004		
Removed concurrent use of insulin with Saxenda use. Reference updated.	07.06.20	07.20

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.

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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.

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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.

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