Health Net

Prior Authorization Protocol

ADIPEX-P®, LOMAIRA™, SUPRENZA® (phentermine), BELVIQ®, BELVIQ XR® (lorcaserin hydrochloride), CONTRAVE® (bupropion SR/naltrexone SR), DESOXYN® (methamphetamine), QSYMIA® (phentermine and topiramate extended release), XENICAL®, ALLI® (orlistat), REGIMEX™, DIDREX® (benzphetamine hydrochloride), TENUATE®, TENUATE® DOSPAN® (diethylpropion hydrochloride), SAXENDA® (liraglutide)

NATL

NOTE: Alli, Tenuate, and Didrex are benefit exclusions for HN-California

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- 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, Suprenza) 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/m^2 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).
- 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.

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- 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).

II. **Health Net Approved Indications and Usage Guidelines:**

Exogenous Obesity:

- Body Mass Index (BMI) is $\geq$ 30 kg/m^2
  OR
- Body Mass Index (BMI) is $\geq$ 27 kg/m^2 with one or more of the following weight related conditions such as:
- Coronary artery/heart disease
  - Diabetes
  - Dyslipidemia
  - Hypertension
  - Obstructive sleep apnea

AND

- Documentation of the patient's baseline weight is required to determine response to therapy

AND

- For phentermine and methamphetamine requests only: Failure or clinically significant adverse events to Xenical®

Attention Deficit Hyperactivity Disorder (ADHD) – for methamphetamine only:

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- Diagnosis of ADHD

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature.

IV. 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.
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- Limitations 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.
- Contrave has increased risk of serious neuropsychiatric events and suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.
- Saxenda is not indicated for the treatment of type 2 diabetes and should not be used in combination with any other glucagon-like peptide-1 receptor agonist or insulin.
- 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 ≤16 years of age have not been established. The use of this product to treat pediatric obesity is not recommended.
  - Belviq, Belviq XR, Contrave or Saxenda – Safety and effectiveness in pediatric patients below the age of 18 have not been established and the use of Belviq, Contrave or Saxenda 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.

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- 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. Therapeutic Alternatives:

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vi. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Xenical	120 mg PO TID with each main meal containing fat	6 month initial trial. **HNCA/HNMC:** Reauthorization will require documentation of a 5% weight loss during the previous 6 month period for the first year of treatment Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance. **NATL:** Reauthorization will require documentation of a 5% weight loss during the previous 6 month period for the first year of treatment, and continuation in a formalized weight management program. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance, and continuation in a formalized weight management program.
phentermine (Adipex-P)	37.5 mg PO QD before breakfast or 1 to 2 hours after breakfast	3 months. Phentermine is only indicated for short term use (8 to 12 weeks).

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Drug	Dosing Regimen	Authorization Limit
Lomaira	8 mg PO TID ½ hour before meals	3 months. Phentermine is only indicated for short term use (8 to 12 weeks).
Suprenza	15 to 37.5 mg dissolved PO on tongue QD in the morning	3 months. Phentermine is only indicated for short term use (8 to 12 weeks).
Belviq Belviq XR	10 mg PO BID 20 mg PO QD	3 months If > 5% weight loss is not achieved at week 12, then drug must be discontinued. If > 5% weight loss is achieved then an additional 12 weeks will be approved. **HNCA/HNMC:** Reauthorization: Documentation of a 5% weight loss during the previous 6 month period for the first year of treatment Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance. **NATL:** Reauthorization: Documentation of a 5% weight loss during the previous 6 month period for the first year of treatment, and continuation in a formalized weight management program. Therapy beyond the first year can be authorized every 6 months with

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Drug	Dosing Regimen	Authorization Limit
		documentation of weight maintenance, and continuation in a formalized weight management program.
Desoxyn	Exogenous obesity: For patients ≥ 12 yo: 5 mg PO 30 minutes before each meal. ADHD: 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 weekly intervals. The usual effective dose is 20-25 mg daily.The total daily dose may be given in two divided doses.	ADHD: Length of Benefit Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy. Exogenous obesity: **HNCA/HNMC:** Initial authorization for 1 month. Reauthorization for 3 months/fill will require documentation of weight reduction **NATL:** Initial authorization for 1 month. Reauthorization for 3 months/fill will require documentation of weight reduction and continuation in a formalized weight management program.
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	Initial: 12 weeks If 3% weight loss is not achieved after 12 weeks on 7.5 mg/46 mg, then dose must be escalated or drug discontinued. **HNCA/HNMC:** If dose is escalated, an additional 12 weeks

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Drug	Dosing Regimen	Authorization Limit
	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. 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.	will be approved. If a 3% weight loss is achieved after 12 weeks of therapy, an additional 12 weeks will be approved. Subsequent reauthorization every 6 months for the first year will require documentation of at least 5% weight loss from baseline body weight. Reauthorization beyond the first year and every 6 months will require documentation of weight maintenance. **NATL:** If dose is escalated, an additional 14 weeks will be approved. If a 3% weight loss is achieved after 12 weeks of therapy, an additional 12 weeks will be approved. Subsequent reauthorization every 6 months for the first year will require documentation of at least 5% weight loss from baseline body weight and continuation in a formalized weight management program. Reauthorization beyond the first year and every 6 months will require documentation of weight maintenance and continuation in a formalized weight management program.
Contrave	8/90 mg PO QAM for one	16 weeks

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Drug	Dosing Regimen	Authorization Limit
	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 (week4).	Reauthorization: If > 5% weight loss is not achieved by week 16, then drug must be discontinued. If > 5% weight loss is achieved then an additional 12 weeks will be approved. **HNCA/HNMC:** Subsequent Reauthorizations: Documentation of a 5% weight loss during the previous 6 month period for the first year of treatment. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance. **NATL:** Subsequent Reauthorizations: Documentation of a 5% weight loss during the previous 6 month period for the first year of treatment and continuation in a formalized weight management program. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance and continuation in a formalized weight management program.
Alli	60 mg PO TID with each main meal containing fat	6 month initial trial. **HNMC:** Reauthorization: Documentation of a 5-10 pound weight loss during the previous 6 month period for the

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Drug	Dosing Regimen	Authorization Limit
		first year of treatment. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance. **NATL:** Reauthorization: Documentation of a 5-10 pound weight loss during the previous 6 month period for the first year of treatment, and continuation in a formalized weight management program. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance and continuation in a formalized weight management program.
Tenuate	25 mg IR tablet PO TID, 1 hour before meals	3 months Tenuate is only indicated for short term use (8 – 12 weeks).
Tenuate Dospan	75 mg CR tablet PO QD mid-morning	3 months Tenuate Dospan is only indicated for short term use (8 – 12 weeks).
Didrex, Regimex	25-50 mg PO QD-TID	3 months Didrex and Regimex are only indicated for short term use (8 – 12 weeks).
Saxenda	3 mg SC QD Start with 0.6mg QD for 1 week and increase by 0.6mg increments per week until 3mg QD is reached.	16 weeks **HNCA/HNMC:** Reauthorization: If patient has not lost at least 4% of baseline body weight by week 16, then drug must be

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Drug	Dosing Regimen	Authorization Limit
		discontinued. If ≥ 4% weight loss is achieved then an additional 36 weeks will be approved. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance. **NATL:** Reauthorization: If patient has not lost at least 4% of baseline body weight by week 16, then drug must be discontinued. If ≥ 4% weight loss is achieved then an additional 36 weeks will be approved with continuation in a formalized weight management program. Therapy beyond the first year can be authorized every 6 months with documentation of weight maintenance and continuation in a formalized weight management program.

VII. Product Availability:

Adipex-P: 37.5 mg capsule and tablet
Lomaira: 8 mg tablet
Suprenza: 15 mg, 30 mg, 37.5 mg orally disintegrating tablet
Desoxyn: 5 mg tablet
Qsymia: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg capsule
Phentermine: 15 mg, 30 mg, 37.5 mg capsule; 37.5 mg tablet
Belviq: 10 mg tablet
Belviq XR: 20 mg extended-release tablet
Contrave: 8 mg naltrexone/90 mg bupropion extended-release tablet
Xenical: 120 mg capsule
Alli: 60 mg capsule

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Tenuate: 25 mg immediate-release (IR) tablet
Tenuate Dospan: 75 mg controlled-release (CR) tablet
Didrex: 50 mg tablet
Regimex: 25 mg tablet
Saxenda: 6mg/mL, 3mL pre-filled, multi-dose pens in a box of 5 pens

VIII. References:

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8. Alli [Drug Facts] Moon Township, PA: GlaxoSmithKline, May 2016.
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Health Net®

Prior Authorization Protocol

ADIPEX-P®, LOMAIRA™, SUPRENZA® (phentermine), BELVIQ®, BELVIQ XR® (lorcaserin hydrochloride), CONTRAVE® (bupropion SR/naltrexone SR), DESOXYN® (methamphetamine), QSYMIA® (phentermine and topiramate extended release), XENICAL®, ALLI® (orlistat), REGIMEX™, DIDREX® (benzphetamine hydrochloride), TENUATE®, TENUATE® DOSPAN® (diethylpropion hydrochloride), SAXENDA® (liraglutide)

NATL

NOTE: Alli, Tenuate, and Didrex are benefit exclusions for HN-California

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.

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