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Medical Necessity for Morbid obesity (Class III Obesity)- CA MKP ONLY

PRODUCTS AFFECTED

Saxenda (liraglutide), Wegovy (semaglutide), Plenity (Carboxymethylcellulose-Cellulose-Citric Acid), Xenical/Alli (orlistat), phentermine, Qysmia (phentermine-topiramate, Contrave (bupropion-naltrexone), Plenity (Carboxymethylcellulose-Cellulose-Citric Acid)], Zepbound

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes.

Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Morbid obesity (Class III Obesity)

REQUIRED MEDICAL INFORMATION:

Drugs used for weight loss are excluded from coverage for overweight/obesity per Social Security 1927 (d)(3)(A).

A State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is contained in the list:

- **Agents when used for anorexia, weight loss, or weight gain.**
- *Agents when used to promote fertility.*
- *Agents when used for cosmetic purposes or hair growth.*
- *Agents when used for the symptomatic relief of cough and colds.*
- *Agents when used to promote smoking cessation.*
- *Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.*
- *Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration*

Drug and Biologic Coverage Criteria

under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

- *Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.*
- *Barbiturates.*
- *Benzodiazepines.*
- *Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.*

The EXCEPTION to this for CLASS III OBESITY (formerly known as morbid obesity) only

A. CLASS III OBESITY:

1. Prescriber attests that member has attempted to lose weight in a formalized weight management program (including hypocaloric diet, exercise and behavior modification) with continuing follow-up for at least 3 months before using drug therapy.
AND
2. Prescriber attests that member is currently enrolled in a supervised weight loss program (e.g., Weight Watchers, nutrition coach, wellness supervisory) that encourages behavioral modification, increased physical activity (if not contraindicated by severe obesity/co-morbidity) and non-pharmacologic weight loss.
AND
3. Documentation of the member's baseline weight is required to determine response to therapy (within the last 30-60 days)
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Saxenda (liraglutide), include: Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2, Hypersensitivity to liraglutide or any excipients in SAXENDA, Pregnancy, Contraindications to Wegovy (semaglutide) include: Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 Known hypersensitivity to semaglutide or any of the excipients in WEGOVY, Contraindications to QSYMIA (phentermine and topiramate extended-release) include: Pregnancy, Glaucoma, Hyperthyroidism, During or within 14 days of taking monoamine oxidase inhibitors, Known hypersensitivity or idiosyncrasy to sympathomimetic amines, Contraindications to orlistat include: Pregnancy, Chronic malabsorption syndrome, Cholestasis, Known hypersensitivity to XENICAL or to any component of this product, Contraindications to Contrave (naltrexone/bupropion) include: Uncontrolled hypertension, Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs, Use of other bupropion-containing products, Chronic opioid use, During or within 14 days of taking monoamine oxidase inhibitors (MAOI), Known allergy to any of the ingredients in CONTRAVE, Contraindications to ZEPBOUND (tirzepatide) include Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 Known hypersensitivity to tirzepatide or any of the excipients in ZEPBOUND]
AND
5. (a) Member currently has a BMI ≥ 40 kg/m² OR (b) BMI ≥ 35 kg/m² for those with obesity-related health conditions (e.g. diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea)
AND
6. FOR MEMBERS WITH TYPE 2 DIABETES: Documented trial and inadequate response to ALL formulary GLP1 or GLP1/GIP agents indicated for diabetes. [Inadequate response is defined as not achieving expected A1c lowering goal while adherent to therapy and not achieving member individualized goals for therapy (e.g., A1c, weight management, maintaining blood glucose within

Drug and Biologic Coverage Criteria

the target range, preventing or reducing hospitalization due to hyper-or hypo-glycemic events, etc.)

CONTINUATION OF THERAPY:

A. CLASS III OBESITY:

1. Documentation member has lost or maintained $\geq 10\%$ of baseline body weight
AND
2. The prescriber attests that the member continues to be compliant with a formalized weight management program.
AND
3. FOR AUTHORIZATIONS OF > 12 MONTHS OF CONTINUOUS SAXENDA OR WEGOVY THERAPY: Documentation of weight maintenance and continuation in a formalized weight management program

****If the member has not lost at least 10% of baseline body weight by week 24, then the drug must be discontinued.

DURATION OF APPROVAL:

Initial Authorization: 6 months, Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

Saxenda (liraglutide), Qsymia (phentermine +topiramate), Xenical (orlistat), Wegovy (semaglutide): 12 years of age and older

All others: 18 years of age and older

QUANTITY:

Saxenda (liraglutide): maximum 3 mg (0.5ml) daily dose- 5 pens per 30 days.

Wegovy (semaglutide): maximum of 2.4mg (0.75ml) daily dose – 5 pens per 30 days

Zepbound (tirzepatide): maximum of 15 mg SC once weekly- 4 pens per 28 days

All others: maximum FDA labeled quantity limits

1 month supply per dispense

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous and oral

DRUG CLASS:

Anti-Obesity Agents

FDA-APPROVED USES:

Plenity (Carboxymethylcellulose-Cellulose-Citric Acid) is indicated to aid in weight management in overweight and obese adults with a body mass index (BMI) of 25-40 kg/m², when used in conjunction with diet and exercise

Wegovy (semaglutide) 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/m² or

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Drug and Biologic Coverage Criteria

greater (obesity) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

Limitations of Use:

WEGOVY™ should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist. The safety and efficacy of coadministration with other products for weight loss have not been established. WEGOVY™ has not been studied in patients with a history of pancreatitis.

Saxenda (liraglutide) 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/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia)

Pediatric patients aged 12 years and older with: body weight above 60 kg and an initial BMI corresponding to 30 kg/m² for adults (obese) by international cut-offs.

Limitations of Use: SAXENDA® contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist. The safety and effectiveness of SAXENDA® in pediatric patients with type 2 diabetes have not been established. The safety and efficacy of SAXENDA® in combination with other products intended for weight loss have not been established

CONTRAVE (naltrexone hydrochloride and bupropion hydrochloride) 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/m² or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

QSYMIA (phentermine and topiramate extended-release) 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) (1) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia

Xenical/Alli (orlistat) is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet

ZEPBOUND (tirzepatide): 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 (obesity) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX: NA

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Disease state Obesity, a complex, multi-factorial condition is usually defined as a body mass index(BMI) ≥ 30 kg/m² and is a fast growing epidemic among adults, adolescents and children. It increases the risk of morbidity and mortality from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke,

Drug and Biologic Coverage Criteria

gallbladder disease, osteoarthritis, sleep apnea, respiratory problems.³ The World Gastroenterology Organization Global Guidelines on Obesity (2012) state that the first treatment step is the basis for every subsequent step and consists of a diet, a less sedentary lifestyle, exercise, and behavioral modification. If weight loss of 5% to 10% is not achieved within 6 months, the next step is the same basic treatment combined with medication. The last step is again a diet, a less sedentary lifestyle, exercise, and behavioral modification, but now combined with bariatric surgery.⁴ A review on treatment of obesity (U.S., 2013) suggests keeping records of food intake and physical activity are the most important tasks for weight loss. A calorie deficit diet, with 50-60% of calories from complex carbohydrates, should be the first choice for most patients. Pharmacotherapy is appropriate for selected patients with obesity, with appropriate monitoring for potential side effects. Bariatric surgery is the most effective and the most high-risk treatment for severe obesity; it has been shown to improve and occasionally cure comorbid conditions and may reduce mortality from excess weight.¹⁸ While the currently approved agents lorcaserin, phentermine/topiramate, and orlistat have produced modest amounts of weight loss after 1 year of treatment, clinical outcome studies demonstrating the long-term effects of these antiobesity agents on morbidity and mortality have not been performed. review on management of obesity (2012) suggests that dietary and physical activity interventions, alone or in combination, are effective for losing weight, and adding psychological interventions improves their success. Strategies to help patients maintain their weight loss for the long term include a high level of physical activity, a diet low in calories and fat, eating breakfast daily, and self-monitoring weight. Pharmacologic treatment of obesity has changed very little recently. The American College of Physicians' guidelines for the management of obesity in primary care recommend that pharmacotherapy be considered for patients with a BMI of >30 kg/m² who have been unable to achieve weight-loss goals through diet and exercise. Patients with a BMI of 27.0–29.9 kg/m² and an obesity-related comorbidity may also benefit from pharmacologic treatment.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

Contraindications to Saxenda (liraglutide), include: Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2, Hypersensitivity to liraglutide or any excipients in SAXENDA, Pregnancy, Contraindications to Wegovy (semaglutide) include: Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 Known hypersensitivity to semaglutide or any of the excipients in WEGOVY, Contraindications to QSYMIA (phentermine and topiramate extended-release) include: Pregnancy, Glaucoma, Hyperthyroidism, During or within 14 days of taking monoamine oxidase inhibitors, Known hypersensitivity or idiosyncrasy to sympathomimetic amines, Contraindications to orlistat include: Pregnancy, Chronic malabsorption syndrome, Cholestasis, Known hypersensitivity to XENICAL or to any component of this product, Contraindications to Contrave (naltrexone/bupropion) include: Uncontrolled hypertension, Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs, Use of other bupropion-containing products, Chronic opioid use, During or within 14 days of taking monoamine oxidase inhibitors (MAOI), Known allergy to any of the ingredients in CONTRAVE, Contraindications to ZEPBOUND (tirzepatide) include Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 Known hypersensitivity to tirzepatide or any of the excipients in ZEPBOUND

COMPOUNDED PRODUCTS ARE NOT APPROPRIATE TO BE REVIEWED WITH THIS POLICY- PLEASE SEE Global Compounded Product C20382-A

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Alli CAPS 60MG, Contrave TB12 8-90MG, Saxenda SOPN 18MG/3ML, Wegovy SOAJ 0.25MG/0.5ML, Wegovy SOAJ 0.5MG/0.5ML, Wegovy SOAJ 1.7MG/0.75ML, Wegovy SOAJ 1MG/0.5ML, Wegovy SOAJ 2.4MG/0.75ML, Xenical CAPS 120MG, Qsymia CP24 3.75-23MG, Qsymia CP24 7.5-46MG, Qsymia CP24 11.25-69MG, Qsymia CP24 15-92MG, Plenity CAPS, Plenity Welcome Kit CAPS, Orlistat CAPS 120MG, Zepbound SOAJ 10MG/0.5ML, Zepbound SOAJ 12.5MG/0.5ML, Zepbound SOAJ 15MG/0.5ML, Zepbound SOAJ 2.5MG/0.5ML, Zepbound SOAJ 5MG/0.5ML, Zepbound SOAJ 7.5MG/0.5ML

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Drug and Biologic Coverage Criteria