PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ANTIOBESITY AGENTS**
BRAND NAME (generic)	
	benzphetamine products
	diethylpropion products
	phendimetrazine products
	phentermine products
Type: Initial Prior Authorization with Quantity Limit	

POLICY

FDA-APPROVED INDICATIONS

Adipex-P, Lomaira, Phentermine

Phentermine is indicated as a short-term (a few weeks) adjunct 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 greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

Benzphetamine

Benzphetamine hydrochloride tablets, USP are 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 body mass index (BMI) of 30 kg/m^2 or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The limited usefulness of agents of this class should be weighed against possible risks inherent in their use. Benzphetamine hydrochloride tablets, USP are indicated for use as monotherapy only.

Diethylpropion

Diethylpropion hydrochloride tablets, 25 mg 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 body mass index (BMI) of 30 kg/m^2 or higher and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The usefulness of agents of this class should be measured against possible risk factors inherent in their use. Diethylpropion hydrochloride tablets, 25 mg are indicated for use as monotherapy only.

Diethylpropion hydrochloride extended release tablets, 75 mg 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 body mass index (BMI) of 30 kg/m^2 or higher and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The usefulness of agents of this class should be measured against possible risk factors inherent in their use. Diethylpropion hydrochloride extended release tablets, 75 mg are indicated for use as monotherapy only.

Phendimetrazine

Phendimetrazine tartrate is 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 body mass index (BMI) of 30 kg/m^2 or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. Phendimetrazine tartrate is indicated for use as monotherapy only.

Phendimetrazine tartrate extended-release capsules 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 body mass index (BMI) of greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen (diet

and/or exercise) alone. The usefulness of agents of this class should be measured against possible risk factors inherent in their use. Phendimetrazine tartrate is indicated for use as monotherapy only.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has not received 3 months of therapy with the requested drug within the past 365 days

AND

- The requested drug will be used with a reduced calorie diet and increased physical activity in the management of exogenous obesity

AND

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

  AND

  - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

  OR

  - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]

    AND

    - The patient has at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [Documentation is required for approval.]

AND

- The request is for phentermine

  AND

  - The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) [NOTE: Due to well documented potential for serious adverse effects, phentermine and fenfluramine are not recommended to be used concurrently.]

Quantity Limits apply.

QUANTITY LIMIT

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

Drug	Dosage	1 Month Limit*	3 Month Limit*
Adipex-P (phentermine)	37.5 mg	30 units / 25 days	90 units / 75 days
Benzphetamine	50 mg	90 tablets / 25 days	270 tablets / 75 days
Diethylpropion	25 mg IR	90 tablets / 25 days	270 tablets / 75 days
	75 mg ER	30 tablets / 25 days	90 tablets / 75 days
Lomaira (phentermine)	8 mg	90 tablets / 25 days	270 tablets / 75 days
Phendimetrazine	35 mg IR	180 tablets / 25 days	540 tablets / 75 days
	105 mg ER	30 capsules / 25 days	90 capsules / 75 days
Phentermine	15 mg	60 capsules / 25 days	180 capsules / 75 days
	30 mg	30 capsules / 25 days	90 capsules / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 18-A: DOA: 3 months (90 days of therapy) per year

REFERENCES

1. Adipex-P [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2020.
2. Benzphetamine [package insert]. Newtown, PA: KVK-Tech, INC.; June 2022.

3. Diethylpropion hydrochloride [package insert]. Congers, NY: Chartwell RX, LLC..; March 2023.
4. Diethylpropion hydrochloride ER [package insert]. Congers, NY: Chartwell RX, LLC.; March 2023.
5. Lomaira [package insert]. Newtown, PA: KVK-Tech, Inc.; December 2018.
6. Phendimetrazine [package insert]. Newtown, PA: KVK-TECH, INC.; September 2019.
7. Phendimetrazine extended-release [package insert]. Langhorne, PA: Virtus Pharmaceuticals, LLC; March 2021.
8. Phentermine hydrochloride [package insert]. Rahway, NJ: Sunrise Pharmaceutical, Inc.; April 2022.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
10. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
11. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2023).
12. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
13. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(2):342–362.
14. FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen). July 2005. Available at: https://wayback.archive-it.org/7993/20170723090512/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm. Accessed May 10, 2023.

STEP THERAPY CRITERIA

BRAND NAME
(generic)

BREXAFEMME
(ibrexafungerp)

Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Brexafemme is indicated in adult and post-menarchal pediatric females for:
- Treatment of vulvovaginal candidiasis (VVC)
- Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

INITIAL STEP THERAPY with QUANTITY LIMIT*
***Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 1-day supply of generic fluconazole within the past 180 days then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.
**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

****INITIAL LIMIT CRITERIA**
Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

Drug	Limit*
Brexafemme (ibrexafungerp)	4 tablets / 7 days

**** This drug is for short-term, acute use.***

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is being prescribed for the treatment of vulvovaginal candidiasis (VVC)

OR
- The requested drug is being prescribed for reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)

AND
- The requested drug is being prescribed for an adult or post-menarchal pediatric patient

AND
  - The patient has experienced an inadequate treatment response to a course of therapy with fluconazole

  OR
  - The patient has experienced an intolerance to fluconazole

  OR

- The patient has a contraindication that would prohibit a trial of fluconazole

AND

- The requested drug is not being used in a footbath

Quantity Limits apply.
Vulvovaginal candidiasis: 4 tablets per 7 days
Recurrent vulvovaginal candidiasis: 4 tablets per 25 days* or 12 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

1. Brexafemme [package insert]. Jersey City, NJ: SCYNEXIS, Inc.; November 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed December 5, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed December 5, 2022.
4. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the infectious diseases society of America. *Clin Infect Dis*. 2016;62(4):e1-e50.
5. Paladine HL, Desai UA. Vaginitis: diagnosis and treatment. *Am Fam Physician*. 2018;97(5):321-329.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**CONTINUOUS GLUCOSE MONITORS**
BRAND NAME (generic)	**DEXCOM (ALL PRODUCTS)** **FREESTYLE LIBRE (ALL PRODUCTS)**

Type: Initial Prior Authorization

POLICY

COVERAGE CRITERIA

The requested continuous glucose monitor and associated accessories will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of diabetes mellitus
  AND
  - The patient is using an intensive insulin regimen [Note: An intensive insulin regimen is defined as multiple daily injections (i.e., 3 or more injections per day) or insulin pump therapy]
    AND
    - The request is NOT for continuation of therapy
      AND
      - The patient is less than 18 years of age

      OR
      - The patient is not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness)

    OR
    - The request is for continuation of therapy
      AND
      - The patient has experienced improved glycemic control or decreased hypoglycemia episodes while using a continuous glucose monitor (CGM)

      OR
      - The patient is being assessed every six months by the prescriber for adherence to their continuous glucose monitor (CGM) regimen and diabetes treatment plan

OR

- The patient has a diagnosis of glycogen storage disease

REFERENCES

1. El Sayed NA, Aleppo G, Aroda VR et. al. American Diabetes Association, Standards of Care in Diabetes – 2023. *Diabetes Care.* 2023;46(Suppl. 1):S1-S291.

2. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus. *Endocr Pract.* 2021;27(6):505-537.
3. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. *Endocr Pract.* 2022; 28(10):923-1049.
4. Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. *Diabetes Care.* 2017;40(12):1631-1640.
5. Centers for Medicare and Medicaid. Local Coverage Determination (LCD) for Glucose Monitors (L33882); Revision Effective Date 01/01/2023. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822&ver=48&. Accessed March 10, 2023.
6. Kaiser N, Gautschi M, Bosanka L, et al. Glycemic control and complications in glycogen storage disease type I: Results from the Swiss registry. *Mol Genet Metab.* 2019;126(4):355-361.
7. Herbert M, Pendyal S, Rairkar M, et al. Role of continuous glucose monitoring in the management of glycogen storage disorders. *J Inherit Metab Dis.* 2018;41(6):917-927.
8. White FJ, Jones SA. The use of continuous glucose monitoring in the practical management of glycogen storage disorders. *J Inherit Metab Dis.* 2011;34(3):631-642.
9. Kasapkara CS, Cinasal Demir G, Hasanoglu A, et al. Continuous glucose monitoring in children with glycogen storage disease type I. *Eur J Clin Nutr.* 2014;68(1):101-105.
10. National Organization for Rare Disorders. Glycogen Storage Disease Type I. Available at: https://rarediseases.org/rare-diseases/glycogen-storage-disease-type-i/. Accessed March 10, 2023.

QUANTITY LIMIT CRITERIA

DRUG CLASS	**DIABETIC CONTINUOUS GLUCOSE MONITOR SENSORS**
BRAND NAME (generic)	**DEXCOM (ALL PRODUCTS)** **FREESTYLE LIBRE (ALL PRODUCTS)**
Type: Quantity Limit	

POLICY

INITIAL LIMIT QUANTITY

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength

Drug	**1 Month Limit***	**3 Month Limit***
Dexcom G6	3 sensors / 25 days	9 sensors / 75 days
Dexcom G7	3 sensors / 25 days	9 sensors / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Drug	**4 Week Limit****	**12 Week Limit****
Freestyle Libre 2	2 sensors / 21 days	6 sensors / 63 days
Freestyle Libre 3	2 sensors / 21 days	6 sensors / 63 days
Freestyle Libre 14-Day	2 sensors / 21 days	6 sensors / 63 days

***The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*

REFERENCES

1. Dexcom G6 Continuous Glucose Monitoring System User Guide. San Diego, CA: Dexcom, Inc.; March 2022. Available at: https://s3-us-west-2.amazonaws.com/dexcompdf/G6-CGM-Users-Guide.pdf. Accessed March 20, 2023.
2. Dexcom G7 Continuous Glucose Monitoring System User Guide. San Diego, CA: Dexcom, Inc.; December 2022 Available at: https://dexcompdf.s3.us-west-2.amazonaws.com/en-us/G7-CGM-Users-Guide.pdf. Accessed March 20, 2023.
3. FreeStyle Libre 2 Flash Glucose Monitoring System User's Manual. Alameda, CA: Abbott Diabetes Care Inc.; November 2021. Available at: https://freestyleserver.com/Payloads/IFU/2021/q4/ART44417-001_rev-A-WEB.pdf. Accessed March 20, 2023.
4. Freestyle Libre 3 Continuous Glucose Monitoring System Quick Reference Guide. Alameda, CA: Abbott Diabetes Care Inc.; March 2022. Available at: https://freestyleserver.com/Payloads/IFU/2022/q2/ART44140-002_rev-A.pdf. Accessed March 20, 2023.
5. FreeStyle Libre 14-Day Flash Glucose Monitoring System User's Manual. Alameda, CA: Abbott Diabetes Care Inc.; August 2018. Available at: https://freestyleserver.com/Payloads/IFU/2018/ART39764-001_rev-A-Web.pdf. Accessed March 20, 2023.

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **CONDOMS**

BRAND NAME (generic)

FEMALE CONDOMS (OTC)

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

INDICATIONS AND USES

Female (internal) condoms are used for the prevention of pregnancy. Female condoms can also effectively protect against sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) transmission.[2-3] Specifically, the FC2 Female Condom is indicated for preventing pregnancy, HIV/AIDs and other sexually transmitted infections(STIs).[1]

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit*	3 Month Limit*
Female Condoms	12 condoms / 25 days	36 condoms / 75 days

** The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient requires more than 12 condoms per month due to a clinical need (e.g., increased sexual activity, condom breakage, or other need to have multiple condoms available for each sexual encounter)

Quantity Limits apply.
24 condoms / 25 days* or 72 condoms / 75 days*.
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

1. FC2 Female Condom Leaflet. Miami, FL: Veru Inc.; November 2021. Available at: https://fc2.us.com/wp-content/uploads/2022/04/FC2-Female-Condom-Product-Leaflet-G0073-1.pdf . Accessed March 14, 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed March 14, 2023.
3. Colquitt CW, Martin TS. Contraceptive Methods: A Review of Nonbarrier and Barrier Products. *Journal of Pharmacy Practice*. 2017;30(1):130-135.
4. Eisenberg ML, Shindel AW, Smith JF, et al. Socioeconomic, Anthropomorphic, and Demographic Predictors of Adult Sexual Activity in the United States: Data from the National Survey of Family Growth. *J Sex Med.* 2010;7(1):50-58.
5. Twenge JM, Sherman RA, Wells BE. Declines in Sexual Frequency Among American Adults, 1989–2014. *Arch Sex Behav*. 2017;46(8):2389-2401.

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **CONDOMS**

BRAND NAME (generic)

MALE CONDOMS (OTC)

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

USES

Male (external) condoms are used for the prevention of pregnancy. Some male condoms (e.g., latex condoms, polyisoprene condoms, polyurethane condoms) can also be used to reduce the spread of sexually transmitted infections (STIs). Lambskin condoms (also known as sheep skin condoms or natural condoms) are only effective as a barrier method for contraception and do not protect against the transmission of STIs.[1-2]

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit*	3 Month Limit*
Male Condoms	12 condoms / 25 days	36 condoms / 75 days

** The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient requires more than 12 condoms per month due to a clinical need (e.g., increased sexual activity, condom breakage, or other need to have multiple condoms available for each sexual encounter)

Quantity Limits apply.
24 condoms / 25 days* or 72 condoms / 75 days*.
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

1. Colquitt CW, Martin TS. Contraceptive Methods: A Review of Nonbarrier and Barrier Products. *Journal of Pharmacy Practice*. 2017;30(1):130-135.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed March 14, 2023.
3. Eisenberg ML, Shindel AW, Smith JF, et al. Socioeconomic, Anthropomorphic, and Demographic Predictors of Adult Sexual Activity in the United States: Data from the National Survey of Family Growth. *J Sex Med.* 2010;7(1):50-58.
4. Twenge JM, Sherman RA, Wells BE. Declines in Sexual Frequency Among American Adults, 1989–2014. *Arch Sex Behav*. 2017;46(8):2389-2401.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **WEIGHT LOSS MANAGEMENT**

BRAND NAME (generic)

CONTRAVE
(naltrexone HCl and bupropion HCl extended-release)

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Contrave 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)

Limitations of Use:

- The effect of Contrave on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Contrave in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management in an adult
  AND
  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
    AND
    - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

    OR
    - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]
      AND
      - The patient has at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [Documentation is required for approval.]

  OR
  - The patient has completed at least 4 months of therapy with the requested drug
    AND
    - The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. [Documentation is required for approval.]
      AND
      - Documentation of the patient's weight prior to starting Contrave therapy and the patient's current weight after Contrave therapy, including the date the weights were taken, has been submitted to CVS Health

Quantity Limits apply.
120 tablets per 25 days* or 360 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 1190-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Contrave Extended-Release [package insert]. Brentwood, TN: Currax Pharmaceuticals LLC; December 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2023).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(2):342–362.

QUANTITY LIMIT CRITERIA

DRUG CLASS **DIABETIC TEST STRIPS**

Type: Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
N/A

INITIAL LIMIT QUANTITY
Limits should accumulate across all products up to highest quantity listed.
PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases, the filling limit and day supply may be less than what is indicated.

Product	1 Month Limit*	3 Month Limit*
Diabetic Test Strips	150 test strips / 25 days	450 test strips / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

1. El Sayed NA, Aleppo G, Aroda VR et. al. American Diabetes Association, Standards of Care in Diabetes – 2023. Diabetes Care 2023;46(Suppl. 1):S1-S291.
2. Weinstock RS, Aleppo G, Bailey TS, et al. *The Role of Blood Glucose Monitoring in Diabetes Management*. Arlington (VA): American Diabetes Association; October 2020.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **DIABETIC TEST STRIPS**

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS
N/A

COVERAGE CRITERIA
The requested product will be covered with prior authorization when the following criteria are met:

- The patient is on an intensive insulin regimen (multiple-dose insulin or insulin pump therapy)

Quantity Limits apply.
300 test strips** per 25 days* or 900 test strips** per 75 days*
** The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*
*** Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.*

REFERENCES
1. El Sayed NA, Aleppo G, Aroda VR et. al. American Diabetes Association, Standards of Care in Diabetes – 2023. *Diabetes Care.* 2023;46(Suppl. 1):S1-S291.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

DUROLANE (hyaluronic acid)
EUFLEXXA (1% sodium hyaluronate)
GEL-ONE (cross-linked hyaluronate)
HYALGAN (sodium hyaluronate)
ORTHOVISC (high molecular weight hyaluronan)
SUPARTZ FX (sodium hyaluronate)
SYNOJOYNT (1% sodium hyaluronate)
SYNVISC (hylan G-F 20)
SYNVISC ONE (hylan G-F 20)
TRILURON (sodium hyaluronate)
TRIVISC (sodium hyaluronate)

Type: Initial Prior Authorization

POLICY

FDA-Approved Indication
Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

All other indications are considered experimental/investigational and not medically necessary.

I. CRITERIA FOR INITIAL APPROVAL

Osteoarthritis (OA) of the Knee
Authorization of 12 months may be granted for treatment of osteoarthritis (OA) in the knee when all of the following criteria are met:

A. The diagnosis is supported by radiographic evidence of osteoarthritis of the knee (e.g., joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts) or the member has at least 5 of the following signs and symptoms:
   1. Bony enlargement
   2. Bony tenderness
   3. Crepitus (noisy, grating sound) on active motion
   4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
   5. Less than 30 minutes of morning stiffness
   6. No palpable warmth of synovium
   7. Over 50 years of age
   8. Rheumatoid factor less than 1:40 titer (agglutination method)
   9. Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm^3)

B. The member has knee pain which interferes with functional activities (e.g., ambulation, prolonged standing).
C. The member has experienced an inadequate response or adverse effects with non-pharmacologic treatment options (e.g., physical therapy, regular exercise, insoles, knee bracing, weight reduction).
D. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of an analgesic (e.g., acetaminophen up to 3 to 4 grams per day, non-steroidal anti-inflammatory drugs [NSAIDs], topical capsaicin cream) for at least 3 months.
E. The member has experienced an inadequate response or intolerance or has a contraindication to a trial of intraarticular steroid injections for at least 3 months.
F. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment.

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of osteoarthritis in the knee when all of the following criteria are met:
A. Member meets all criteria for initial approval.
B. Member has experienced improvement in pain and functional capacity following the previous injections.
C. At least 6 months has elapsed since the last injection in the prior completed series of injections.

III. REFERENCES

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QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**OPIOID CONTAINING COUGH AND COLD PRODUCTS (RX AND OTC)**
BRAND NAME (generic)	**HISTEX AC (hydrocodone/homatropine tablet)** **HYDROMET (hydrocodone/homatropine solution)** **POLY-TUSSIN AC (promethazine/codeine) (promethazine/codeine/phenylephrine)** **TUSSIONEX (hydrocodone polistirex/chlorpheniramine polistirex extended-release suspension)** **TUXARIN ER (codeine/chlorpheniramine extended-release tablet)** **TUZISTRA XR (codeine/chlorpheniramine extended-release suspension)**
Type: Quantity Limit; Post Limit Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Hydrocodone and homatropine solution, tablets

Hydrocodone and homatropine is indicated for the symptomatic relief of cough in patients 18 years of age and older.

Limitations of Use:

- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients less than 6 years of age.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve hydrocodone and homatropine for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

Hydrocodone Polistirex and Chlorpheniramine Polistirex Suspension, Extended-Release

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Oral Suspension is indicated for the temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age or older.

Important Limitations of Use

- Not indicated for pediatric patients under 18 years of age.

- Contraindicated in pediatric patients less than 6 years of age.
- Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, reserve Hydrocodone Polistirex and Chlorpheniramine Polistirex for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risk, and in whom an adequate assessment of the etiology of the cough has been made.

Promethazine with codeine oral solution
Promethazine with codeine oral solution is indicated for the temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older.

Limitations of Use:
- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy and/or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve promethazine with codeine oral solution for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

Promethazine, codeine, phenylephrine oral solution
Promethazine, codeine, phenylephrine Oral Solution is indicated for the temporary relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold in patients 18 years of age and older.

Limitations of Use:
- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve promethazine, codeine, phenylephrine oral solution for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

TussiCaps
TussiCaps (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsules are indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older.

Tuxarin ER
Tuxarin ER is indicated for the relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults 18 years of age and older.

Limitations of Use:
- Not indicated for pediatric patients under 18 years of age.

Tuzistra XR
Tuzistra XR is indicated for the temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older.

Limitations of Use:
- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Tuzistra XR for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

OVER-THE-COUNTER PRODUCT USES

CapCof
Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:
- Runny nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes
- Cough due to minor throat and bronchial irritation
- Nasal congestion
- Reduces swelling of nasal passages

Coditussin AC
Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Coditussin DAC
Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- reduces swelling of nasal passages

Histex AC
Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:
- Runny nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes
- Cough due to minor throat and bronchial irritation
- Nasal congestion
- Reduces swelling of nasal passages

Mar-cof BP
Temporarily relieves these symptoms due to cold, hay fever or other respiratory allergies:
- runny nose, sneezing, itching of the nose or throat, and itchy watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion

Mar-cof CG
Temporarily relieves:
- cough due to minor throat and bronchial irritations as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes cough more productive

Maxi-Tuss AC
Temporarily relieves:
- cough due to minor throat and bronchial irritations as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes cough more productive

Maxi-Tuss CD

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages
- calms the cough control center and relieves coughing

M-Clear WC

Temporarily relieves these symptoms due to the common cold:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

M-END PE

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- nasal congestion
- itching of nose or throat
- runny nose
- itchy, watery eyes
- sneezing
- reduces swelling of nasal passages

Ninjacof-XG

Temporarily relieves:

- cough due to minor throat and bronchial irritations
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Poly-Tussin AC

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the nasal passages

Pro-Red AC

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages
- runny nose
- sneezing
- itching of nose or throat
- itchy, watery eyes

Rydex
Temporarily relieves these symptoms due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis):

- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the nasal passages
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Tusnel C
Uses:

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves: nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with sinusitis, cough due to minor bronchial irritation as may occur with the common cold
- temporarily restores freer breathing through the nose
- calms the cough control center and relieves coughing

Virtussin DAC
Uses:

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves nasal congestion due to the common cold
- temporarily restores freer breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- calms the cough control center and relieves coughing

QUANTITY LIMIT**

LIMIT CRITERIA
This limit is coded for daily dose.

Drug	**Daily Limit**
CapCof (codeine/phenylephrine/chlorpheniramine [10 mg-5 mg-2 mg/5 mL] syrup)	60 mL/day
Coditussin AC (codeine/guaifenesin [10 mg-200 mg/5 mL] syrup)	60 mL/day
Coditussin DAC (codeine/guaifenesin/pseudoephedrine [10 mg-200 mg-30 mg/5 mL] syrup)	40 mL/day
Histex AC (codeine/phenylephrine/triprolidine [10 mg-10 mg-2.5 mg/5 mL] syrup)	20 mL/day
(hydrocodone and homatropine [5 mg-1.5 mg/5 mL] solution)	30 mL/day
(hydrocodone and homatropine [5 mg-1.5 mg] tablets)	6 tablets/day
(hydrocodone polistirex and chlorpheniramine polistirex [10 mg – 8 mg/5 mL] suspension, extended-release)	10 mL/day
Mar-cof BP (codeine/pseudoephedrine/brompheniramine [7.5 mg-30 mg-2 mg/5 mL] syrup)	60 mL/day
Mar-cof CG (codeine/guaifenesin [7.5 mg-225 mg/5 mL] syrup)	45 mL/day
Maxi-Tuss AC (codeine/guaifenesin [10 mg-100 mg/5 mL] liquid)	60 mL/day

Maxi-Tuss CD (codeine/phenylephrine/chlorpheniramine [10 mg-10 mg-4 mg/5 mL] liquid)	30 mL/day
M-Clear WC (codeine/guaifenesin [6.33 mg-100 mg/5 mL] liquid)	90 mL/day
M-END PE (codeine/phenylephrine/brompheniramine [6.33 mg-3.33 mg-1.33 mg/5 mL] liquid)	90 mL/day
Ninjacof-XG (codeine/guaifenesin [8 mg-200 mg/5 mL] liquid)	60 mL/day
Poly-Tussin AC (codeine/phenylephrine/brompheniramine [10 mg-10 mg-4 mg/5 mL] liquid)	30 mL/day
(promethazine with codeine [6.25 mg-10 mg/5 mL] oral solution)	30 mL/day
(promethazine, codeine, phenylephrine [6.25 mg-10 mg-5 mg/5 mL] oral solution)	30 mL/day
Pro-RED AC (codeine/dexchlorpheniramine/phenylephrine [9 mg-1 mg-5 mg/5 mL] syrup)	60 mL/day
Rydex (codeine/pseudoephedrine/brompheniramine [6.33 mg-10 mg-1.33 mg/5 mL] liquid)	90 mL/day
Tusnel C (codeine/guaifenesin/pseudoephedrine liquid [10 mg-100 mg-30 mg/5 mL])	40 mL/day
TussiCaps (hydrocodone/chlorpheniramine extended-release [10 mg-8 mg] capsule)	2 capsules/day
Tuxarin ER (codeine/chlorpheniramine extended-release [54.3 mg-8 mg] tablet)	2 tablets/day
Tuzistra XR (codeine/chlorpheniramine [14.7 mg-2.8 mg/5 mL] extended-release suspension)	20 mL/day
Virtussin DAC (codeine/guaifenesin/pseudoephedrine [10 mg-100 mg-30 mg/5 mL] liquid)	40 mL/day

***If the patient is requesting more than the initial quantity limit, then the claim will reject with a message indicating that the daily dose has been exceeded. No PA allowed to exceed daily dose limit.*

DURATION LIMIT*

Drug	Duration Limit (per month)
ALL TARGET DRUGS	7-day supply

**If the patient is requesting more than a 7-day supply within the past month, then the claim will reject with a message indicating that the patient can receive a 7-day supply or submit a prior authorization (PA): "MAX 7 DS per 30 days. PA req call 800-XXX-XXXX." [Note: Benefits coding to populate correct PA phone number.]*

The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a persistent cough requiring treatment beyond 7 days

AND

- The patient has been reevaluated for the cause of the cough to address any underlying pathology, such as foreign body or lower respiratory tract disease

AND

- The need for continued use of the requested drug has been assessed considering the relative incidence of adverse reactions, and the development of addiction, abuse, or misuse

Quantity Limits apply.

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PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

OZOBAX
(baclofen solution)

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Fleqsuvy
Fleqsuvy is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Fleqsuvy may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitations of Use
Fleqsuvy is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Lyvispah
Lyvispah is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity. Lyvispah may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitation of Use
Lyvispah is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Ozobax
Ozobax is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitations of Use
Ozobax is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of spasticity resulting from any of the following: A) multiple sclerosis, B) a spinal cord injury, C) a spinal cord disease (e.g., including but not limited to transverse myelitis, NMOSD, MOGAD)
  AND
- The request is for Lyvispah AND the patient requires administration of the requested drug via enteral feeding tube
  OR

- The patient has difficulty swallowing tablets

Quantity Limits apply.

INITIAL LIMIT QUANTITY

Drug	1 Month Limit*	3 Month Limit*
Ozobax 5 mg/5 mL Oral Solution	2,400 mL / 25 days	7,200 mL / 75 days
Fleqsuvy 25 mg/5 mL (5 mg/mL) Oral Suspension	480 mL / 25 days	1,440 mL / 75 days
Lyvispah 5 mg Oral Granules Single Dose Packets	120 packets / 25 days	360 packets / 75 days
Lyvispah 10 mg Oral Granules Single Dose Packets	120 packets / 25 days	360 packets / 75 days
Lyvispah 20 mg Oral Granules Single Dose Packets	120 packets / 25 days	360 packets / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

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PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**WEIGHT LOSS MANAGEMENT**
BRAND NAME (generic)	**QSYMIA (phentermine and topiramate extended-release)**

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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
- Pediatric patients aged 12 years and older with an initial BMI in the 95th percentile or greater standardized for age and sex.

Limitations of Use

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management

AND

- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) [NOTE: Due to well documented potential for serious adverse effects, phentermine and fenfluramine are not recommended to be used concurrently. Qsymia contains phentermine.]

AND

- The patient has not completed at least 12 weeks of therapy with Qsymia 7.5 mg/46 mg or 15 mg/92 mg

AND

  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

AND

    - The patient is 18 years of age or older

AND

      - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

OR

      - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]

AND

        - The patient has at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [Documentation is required for approval.]

OR

- The patient is 12 to 17 years of age
  AND
  - The patient has an initial body mass index (BMI) in the 95th percentile or greater standardized for age and sex. [Documentation is required for approval.]

OR

- The patient has completed at least 12 weeks of Qsymia 15 mg/92 mg therapy
  AND
  - The patient is 18 years of age or older
    AND
    - The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. [Documentation is required for approval.]
      AND
      - Documentation of the patient's weight prior to starting Qsymia therapy and the patient's current weight after Qsymia therapy, including the dates the weights were taken, has been submitted to CVS Health

    OR
  - The patient is 12 to 17 years of age
    AND
    - The patient has experienced a reduction of at least 5 percent of baseline body mass index (BMI) OR the patient has continued to maintain their initial reduction of 5 percent of baseline body mass index (BMI). [Documentation is required for approval.]
      AND
      - Documentation of the patient's body mass index (BMI) prior to starting Qsymia therapy and the patient's current BMI after Qsymia therapy, including the date the BMIs were taken, has been submitted to CVS Health

OR

- The patient has completed at least 12 weeks of Qsymia 7.5 mg/46 mg therapy
  AND
  - The patient is 18 years of age or older
    AND
    - The patient has lost at least 3 percent of baseline body weight OR the patient has continued to maintain their initial 3 percent weight loss. [Documentation is required for approval.]
      AND
      - Documentation of the patient's weight prior to starting Qsymia therapy and the patient's current weight after Qsymia therapy, including the date the weights were taken, has been submitted to CVS Health

    OR
    - The patient has not lost at least 3 percent of baseline body weight OR the patient has not continued to maintain their initial 3 percent weight loss
      AND
      - The patient's dose has been increased to Qsymia 11.25 mg/69 mg and will follow the appropriate dose escalation schedule. [Documentation is required for approval.]

    OR
  - The patient is 12 to 17 years of age
    AND
    - The patient has experienced a reduction of at least 3 percent of baseline body mass index (BMI) OR the patient has continued to maintain their initial reduction of 3 percent of baseline body mass index (BMI). [Documentation is required for approval.]
      AND
      - Documentation of the patient's body mass index (BMI) prior to starting Qsymia therapy and the patient's current BMI after Qsymia therapy, including the date the BMIs were taken, has been submitted to CVS Health

    OR
    - The patient has not experienced a reduction of at least 3 percent of baseline body mass index (BMI) OR the patient has not continued to maintain their initial reduction of 3 percent BMI
      AND
      - The patient's dose has been increased to Qsymia 11.25 mg/69 mg and will follow the appropriate dose escalation schedule. [Documentation is required for approval.]

Quantity Limits apply.

QUANTITY LIMIT

Drug	Dosage	1 Month Limit*	3 Month Limit*
Qsymia (phentermine/topiramate extended-release)	3.75 mg/23 mg	30 capsules / 25 days	90 capsules / 25 days
	7.5 mg/46 mg		
	11.25 mg/69 mg		
	15 mg/92 mg		

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 794-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Qsymia [package insert]. Campbell, CA: Vivus LLC; June 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2023).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(2):342–362.
6. FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen). July 2005. Available at: https://wayback.archive-it.org/7993/20170723090512/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm. Accessed May 10, 2023.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**WEIGHT LOSS MANAGEMENT**
BRAND NAME (generic)	**SAXENDA (liraglutide injection)**
Type: Initial Prior Authorization with Quantity Limit	

POLICY

FDA-APPROVED INDICATIONS

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)
- Pediatric patients aged 12 years and older with:
  - body weight above 60 kg and
  - an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria)

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 effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management
  AND
  - The patient is 18 years of age or older
    AND
    - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
      AND
      - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

      OR
      - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]
        AND
        - The patient has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia). [Documentation is required for approval.]

    OR
    - The patient has completed at least 16 weeks of therapy with the requested drug
      AND

- The patient has lost at least 4 percent of baseline body weight OR the patient has continued to maintain their initial 4 percent weight loss. [Documentation is required for approval.]
  AND
  - Documentation of the patient's weight prior to starting Saxenda therapy and the patient's current weight after Saxenda therapy, including the date the weights were taken, has been submitted to CVS Health

OR

- The patient is 12 to 17 years of age
  AND
  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
    AND
    - The patient has a body weight above 60 kg. [Documentation is required for approval.]
      AND
    - The patient has an initial body mass index (BMI) corresponding to 30 kg/m^2 or greater for adults by international cut-off points based on the Cole Criteria. [Documentation is required for approval.]

  OR

  - The patient has completed at least 12 weeks of therapy on the maintenance dose of therapy with the requested drug
    AND
    - The patient has had at least 1 percent reduction in body mass index (BMI) from baseline OR the patient has continued to maintain their initial 1 percent reduction in BMI from baseline. [Documentation is required for approval.]
      AND
      - Documentation of the patient's body mass index (BMI) prior to starting Saxenda therapy and the patient's current BMI after Saxenda therapy, including the date the BMIs were taken, has been submitted to CVS Health

Quantity Limits apply.
15 mL (1 package of five 3 mL pens) per 25 days* or 45 mL (3 packages of five 3 mL pens each) per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 1227-C:
  - Adults: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months
  - Pediatrics: Initial therapy DOA: 5 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/10/2023).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(2):342–362.

PRIOR AUTHORIZATION CRITERIA

CLASS **SELECT ARTIFICIAL SALIVA MEDICAL DEVICES**

PRODUCT NAME (brand/generic)
SELECT ARTIFICIAL SALIVA MEDICAL DEVICES RX ONLY

Type: Initial Prior Authorization

POLICY

INDICATIONS[1-8]

Artificial Saliva Medical Devices

- Indicated for dryness of the mouth or throat (hyposalivation, xerostomia, mucositis)
- Indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion, and may be used to help relieve bad taste, relieve offensive nasal discharge, and crusting.
- May be used as part of an oral hygiene program for patients with dry mouth, also provides intensive hygiene of the oral cavity
- Indicated as an adjunct to standard oral care in relieving the discomfort associated with oral mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with amelioration of pain.
- May be used for relief of dryness of the oral mucosa when hyposalivation results from any of the following: surgery, radiotherapy, chemotherapy, infection or dysfunction of the salivary glands, inflammation of the mouth or throat, fever, emotional factors such as fear or anxiety, obstruction of the salivary ducts, Bell's Palsy, Sjogren's syndrome
- Provide relief from dry mouth due to certain diseases, medication use, oral inflammation, chemo or radiotherapy, stress or aging. Relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste.
- Relieves the symptoms of dry mouth by enhancing swallowing, improving speech mechanics, and lubricating the oral cavity like natural saliva.

COVERAGE CRITERIA

The requested medical device will be covered with prior authorization when the following criteria are met:

- The requested product is being prescribed for dryness of the oral mucosa

AND

- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to all over-the-counter (OTC) artificial saliva products (e.g. Biotene, MouthKote, Oasis, Xylimelts)

AND

- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to FDA-approved salivary stimulant drugs (pilocarpine/Salagen, cevimeline/Evoxac)

  OR

- FDA-approved salivary stimulant drugs (pilocarpine/Salagen, cevimeline/Evoxac) are not indicated for the patient's medical condition

REFERENCES

1. Aquoral. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf5/K051812.pdf. Accessed September 2021.

2. Caphosol. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162167.pdf. Accessed September 2020.
3. Neutrasal. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093642.pdf. Accessed September 2021.
4. SalivaMAX. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152406.pdf. Accessed September 2021.
5. Biotene Gel, Rinse, Mouth Spray. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123731.pdf. Accessed September 2021.
6. Oasis Discs.510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/K041563.pdf. Accessed September 2021.
7. MouthKote. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf6/K062653.pdf. Accessed September 2021.
8. Xylimelts. Available at: https://www.oracoat.com/products.html. Accessed September 2021.
9. Salagen [package insert]. Woodcliff Lake, NJ: Eisai Inc.; June 2018.
10. Evoxac [package insert]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc.; February 2022.
11. Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices. Available at: https://www.fda.gov/medical-devices. Accessed August 2022.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic) **TEMODAR**
(temozolomide)

Type: Initial Prior Authorization

POLICY

A. FDA-Approved Indications
   1. Newly Diagnosed Glioblastoma
      Temodar is indicated for the treatment of adult patients with newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment.

   2. Refractory Anaplastic Astrocytoma
      Temodar is indicated for the treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

B. Compendial Uses
   1. Central nervous system (CNS) cancer
   2. Ewing sarcoma
   3. Neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, and thymus
   4. Well-differentiated grade 3 neuroendocrine tumors
   5. Extrapulmonary Poorly differentiated (high grade) neuroendocrine carcinoma/large or small cell carcinoma
   6. Pheochromocytoma/paraganglioma
   7. Cutaneous melanoma
   8. Uveal melanoma
   9. Mycosis fungoides (MF)/Sézary syndrome (SS)
   10. Small cell lung cancer
   11. Soft tissue sarcoma
   12. Uterine sarcoma

All other indications are considered experimental/investigational and not medically necessary.

I. CRITERIA FOR INITIAL APPROVAL

A. Central nervous system (CNS) cancer
Authorization of 12 months may be granted for treatment of CNS cancers.

B. Ewing sarcoma
Authorization of 12 months may be granted for treatment of Ewing sarcoma.

C. Neuroendocrine tumors
Authorization of 12 months may be granted for treatment of neuroendocrine tumors.

D. Extrapulmonary Poorly differentiated (high-grade) neuroendocrine carcinoma/large or small cell carcinoma
Authorization of 12 months may be granted for treatment of extrapulmonary poorly differentiated (high-grade) neuroendocrine carcinoma or large or small cell carcinoma.

E. Pheochromocytoma/paraganglioma
Authorization of 12 months may be granted for treatment of pheochromocytoma or paraganglioma.

F. Cutaneous Melanoma
Authorization of 12 months may be granted for treatment of cutaneous melanoma for metastatic or unresectable disease.

G. Uveal Melanoma
Authorization of 12 months may be granted for treatment of uveal melanoma for distant metastatic disease.

H. Mycosis fungoides (MF)/Sézary syndrome (SS)
Authorization of 12 months may be granted for treatment of MF or SS.

I. Small cell lung cancer (SCLC)
Authorization of 12 months may be granted for treatment of SCLC.

J. Soft tissue sarcoma (STS)
Authorization of 12 months may be granted for treatment of STS.

K. Uterine sarcoma[3]
Authorization of 12 months may be granted for treatment of uterine sarcoma.

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

III. REFERENCES

1. Temodar [package insert]. Rahway, NJ: Merck & Co., Inc.; November 2022.
2. Temozolomide [package insert]. Durham, NC: Accord Healthcare, Inc.; October 2021.
3. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 6, 2023.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

UPNEEQ
(oxymetazoline hydrochloride ophthalmic solution)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Upneeq is indicated for the treatment of acquired blepharoptosis in adults.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of acquired blepharoptosis in an adult patient
  AND
  - The request is NOT for continuation of therapy
    AND
    - The patient is being treated for acquired ptosis which is NOT a result of injury or nerve problems
      AND
    - The patient has a loss of visual field, confirmed by a visual field test (e.g., Goldmann, Humphrey, Leicester) AND a Marginal Reflex Distance 1 (MRD1) of 2 mm or less
      [Documentation is required for approval.]
      AND
    - The prescriber attests the patient is NOT being treated with the requested drug for cosmetic purposes

  OR
  - The request is for continuation of therapy
    AND
    - The patient demonstrated improvement from baseline visual field, confirmed by a visual field test (e.g., Goldmann, Humphrey, Leicester) OR a positive effect in Marginal Reflex Distance 1 (MRD1) from baseline
      [Documentation is required for approval.]

Quantity Limits apply.
30 single-use containers per 25 days* or 90 single-use containers per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*
***For new starts, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one fill at a time for new starts, even if filled at mail order; there should be no 3-month supplies filled for new starts. The duration of 25 days is used for a 30-day filled period to allow time for refill processing.*

Duration of Approval (DOA):

- 5450-C: Initial therapy DOA: 2 months; Continuation of therapy DOA: 12 months

REFERENCES
1. Upneeq [package insert]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; May 2023.

2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed August 4, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/04/2023).
4. American Academy of Ophthalmology (AAO): EyeWiki. Blepharoptosis. Available at: https://eyewiki.aao.org/Blepharoptosis. Last Updated May 27, 2023. Accessed November 3, 2022.
5. American Academy of Ophthalmology (AAO): Eye Health A-Z. What is Ptosis? Available at: https://www.aao.org/eye-health/diseases/what-is-ptosis. Last Updated September 09, 2022. Accessed August 31, 2023.
6. American Academy of Ophthalmology (AAO): First Prescription Fix for Droopy Eyelid. Available at: https://www.aao.org/eye-health/news/first-prescription-fix-droopy-eyelid. Last Updated September 17, 2020. Accessed August 31, 2023.
7. Clinicaltrials.gov. RVL Pharmaceuticals, Inc. Study of Safety and Efficacy of RVL-1201 in the Treatment of Acquired Blepharoptosis. Last Updated October 2021. Retrieved from: https://clinicaltrials.gov/ct2/show/NCT02436759?term=RVL-1201&phase=23&draw=2&rank=2. Accessed August 31, 2023.
8. Clinicaltrials.gov. RVL Pharmaceuticals, Inc. Study of Safety and Efficacy of RVL-1201 in the Treatment of Blepharoptosis. Last Updated September 2020. Retrieved from: https://clinicaltrials.gov/ct2/show/results/NCT03565887?term=oxymetazoline+hydrochloride&type=Intr&cond=%22Blepharoptosis%22&phase=2&draw=1. Accessed August 31, 2023.
9. American Academy of Ophthalmology (AAO): Visual Field Test. Available at: https://www.aao.org/eye-health/tips-prevention/visual-field-testing. Last Updated March 10, 2022. Accessed August 31, 2023.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**WEIGHT LOSS MANAGEMENT**
BRAND NAME (generic)	**WEGOVY (semaglutide injection)**

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Wegovy 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 (obesity) 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)
- pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)

Limitation of Use

- Wegovy contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist.
- The safety and effectiveness of Wegovy in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Wegovy has not been studied in patients with a history of pancreatitis.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for chronic weight management
  AND
  - The patient is 18 years of age or older
    AND
    - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
      AND
      - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

      OR
      - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]
        AND
        - The patient has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [Documentation is required for approval.]

    OR
    - The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose
      AND

- The patient has lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. [Documentation is required for approval.]
  AND
  - Documentation of the patient's weight prior to starting Wegovy therapy and the patient's current weight after Wegovy therapy, including the date the weights were taken, has been submitted to CVS Health

OR

- The patient is 12 to 17 years of age
  AND
  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
    AND
    - The patient has an initial body mass index (BMI) in the 95th percentile or greater standardized for age and sex (obesity). [Documentation is required for approval.]

  OR
  - The request is for continuation of therapy for a patient that has successfully titrated to a stable maintenance dose
    AND
    - The patient has had a reduction from their baseline body mass index (BMI) OR the patient has continued to maintain their reduction in BMI from baseline. [Documentation is required for approval.]
      AND
      - Documentation of the patient's body mass index (BMI) prior to starting Wegovy therapy and the patient's current BMI after Wegovy therapy, including the date the BMIs were taken, has been submitted to CVS Health

Quantity Limits apply.

QUANTITY LIMIT

Drug	Dosage	1 Month Limit	3 Month Limit
Wegovy (semaglutide)	0.25 mg/0.5 mL	2 mL (1 package of 4 pens each) / 21 days*	6 mL (3 packages of 4 pens each) / 63 days*
	0.5 mg/0.5 mL		
	1 mg/0.5 mL		
	1.7 mg/0.75 mL	3 mL (1 package of 4 pens each) / 21 days*	9 mL (3 packages of 4 pens each) / 63 days*
	2.4 mg/0.75 mL		

**The duration of 21 days is used for a 28-day fill period and 63 days is used for a 84-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 4774-C: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com (cited: 05/10/2023).
4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
5. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(2):342–362.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic) **XELODA**
(capecitabine)

Type: Initial Prior Authorization

POLICY

A. FDA-Approved Indications
   1. Colorectal Cancer
      a. Xeloda is indicated as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred.
      b. Xeloda is indicated as first-line treatment in patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred.
   2. Breast Cancer
      a. Xeloda in combination with docetaxel is indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy.
      b. Xeloda monotherapy is also indicated for the treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated, for example, patients who have received cumulative doses of 400 mg/m^2 of doxorubicin or doxorubicin equivalents.
   3. Gastric, Esophageal, or Gastroesophageal Junction Cancer
      a. Xeloda is indicated for the treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen.
      b. Xeloda is indicated for the treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.
   4. Pancreatic Cancer
      Xeloda is indicated for the adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.

B. Compendial Uses
   1. Ampullary Adenocarcinoma
   2. Anal carcinoma
   3. Breast cancer
   4. Central nervous system (CNS) metastases from breast cancer
   5. Colorectal Cancer (including anal adenocarcinoma and appendiceal adenocarcinoma)
   6. Esophageal and esophagogastric junction cancer
   7. Gastric cancer
   8. Head and neck cancers (including very advanced head and neck cancer)
   9. Biliary tract cancers (including extrahepatic and intra-hepatic cholangiocarcinoma and gallbladder cancer)
   10. Occult primary tumors (cancer of unknown primary)
   11. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, mucinous cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor
   12. Pancreatic adenocarcinoma
   13. Penile cancer
   14. Neuroendocrine and adrenal tumors

15. Thymomas and Thymic Carcinomas
16. Gestational Trophoblastic Neoplasia
17. Small bowel adenocarcinoma
18. Squamous cell skin cancer
19. Cervical cancer
20. Endometrial carcinoma
21. Vulvar cancer

All other indications are considered experimental/investigational and not medically necessary.

I. CRITERIA FOR INITIAL APPROVAL

A. Colorectal Cancer (CRC)

Authorization of 12 months may be granted for treatment of colorectal cancer, including anal adenocarcinoma and appendiceal adenocarcinoma.

B. Breast Cancer

Authorization of 12 months may be granted for treatment of breast cancer in members when any of the following criteria are met:

1. Member has human epidermal growth factor receptor 2 (HER2) negative advanced, recurrent unresectable, or metastatic disease or member had no response to preoperative systemic therapy, as a single agent or in combination with docetaxel; or
2. Member has early-stage HER2 negative postoperative residual disease, as a single agent; or
3. Member has HER2 positive advanced, recurrent unresectable, or metastatic disease or member had no response to preoperative systemic therapy, and the requested medication will be used as subsequent therapy in combination with trastuzumab and tucatinib or in combination with a HER2 inhibitor (e.g., margetuximab-cmkb [Margenza], trastuzumab [Herceptin], lapatinib [Tykerb], neratinib [Nerlynx]); or
4. The requested medication will be used in combination with ixabepilone for treatment of metastatic or locally advanced disease; or
5. Member has triple negative disease and meets one of the following criteria:
    a. The requested medication will be used as adjuvant therapy; or
    b. The requested medication will be used as maintenance therapy following adjuvant chemotherapy; or
    c. The requested medication with be used for advanced, recurrent unresectable, or metastatic disease or member had no response to preoperative systemic therapy, as a single agent or in combination with docetaxel
6. Member has brain metastases in breast cancer and the requested medication will be used as initial therapy or for recurrent or relapsed disease.

C. Neuroendocrine and Adrenal Tumors

Authorization of 12 months may be granted for treatment of ANY of the following:

1. Member has neuroendocrine tumors of the gastrointestinal tract, lung, or thymus (carcinoid tumors); or
2. Member has neuroendocrine and adrenal tumors of the pancreas, in combination with temozolomide or as a component of CAPEOX (capecitabine and oxaliplatin) regimen; or
3. Member has extrapulmonary poorly differentiated disease/large or small cell disease/mixed neuroendocrine-non-neuroendocrine neoplasm, in combination with temozolomide or with concurrent or sequential radiation; or
4. Member has well differentiated grade 3 neuroendocrine tumors, in combination with temozolomide or as a component of CAPEOX (capecitabine and oxaliplatin) regimen

D. Pancreatic Adenocarcinoma

Authorization of 12 months may be granted for treatment of pancreatic adenocarcinoma.

E. Esophageal and Esophagogastric Junction Cancers

Authorization of 12 months may be granted for treatment of esophageal and esophagogastric junction cancers.

F. Gastric Cancer

Authorization of 12 months may be granted for treatment of gastric cancer.

G. Biliary Tract Cancers
Authorization of 12 months may be granted for treatment of biliary tract cancers (including extrahepatic and intrahepatic cholangiocarcinoma and gallbladder cancer).

H. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer
Authorization of 12 months may be granted for treatment of ANY of the following:
1. As a single agent therapy for persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, or grade 1 endometrioid carcinoma; or
2. Member has low-grade serous carcinoma/borderline epithelial tumor and the requested medication will be used as a single agent for platinum-sensitive or platinum-resistant recurrence
3. Member has mucinous carcinoma of the ovary and either of the following criteria are met:
    a. The requested medication will be used in combination with oxaliplatin as adjuvant treatment; or
    b. The requested medication will be used as a single agent or in combination with oxaliplatin for treatment of persistent or relapsed/recurrent disease.

I. Head and Neck Cancers
Authorization of 12 months may be granted for treatment of head and neck cancers (including very advanced head and neck cancer), as a single agent.

J. Occult Primary Tumors (cancer of unknown primary)
Authorization of 12 months may be granted for treatment of occult primary tumors, as a single agent or as a component of CAPEOX (capecitabine and oxaliplatin) regimen.

K. Penile Cancer
Authorization of 12 months may be granted for treatment of penile cancer, as a single agent.

L. Anal Carcinoma
Authorization of 12 months may be granted for treatment of anal carcinoma when any of the following criteria are met:
1. The requested drug will be used as concurrent chemoradiation in combination with mitomycin.
2. The requested drug will be used with radiation after primary treatment of metastatic disease, as a single agent.

M. Thymomas and Thymic Carcinomas
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas in combination with gemcitabine.

N. Gestational Trophoblastic Neoplasia
Authorization of 12 months may be granted for treatment of gestational trophoblastic neoplasia, as a single agent.

O. Small Bowel Adenocarcinoma
Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma.

P. Squamous Cell Skin Cancer
Authorization of 12 months may be granted for treatment of squamous cell skin cancer when all of the following criteria are met:
1. Disease is locally advanced, distant metastatic, recurrent, or regional disease that is unresectable, inoperable, incompletely resected
2. Member is ineligible for or has progressed on immune checkpoint inhibitors and clinical trials
3. The requested medication will be used as a single agent.

Q. Ampullary Adenocarcinoma
Authorization of 12 months may be granted for treatment of ampullary adenocarcinoma.

R. Cervical Cancer
Authorization of 12 months may be granted for cervical cancer when all of the following criteria are met:

1. The requested drug will be used as concurrent chemoradiation in combination with mitomycin.
2. The requested drug will be used if cisplatin and carboplatin are unavailable.

S. Endometrial Carcinoma

Authorization of 12 months may be granted for endometrial carcinoma when all of the following criteria are met:

1. The requested drug will be used as primary treatment as concurrent chemoradiation in combination with mitomycin.
2. The requested drug will be used if cisplatin and carboplatin are unavailable.

T. Vulvar Cancer

Authorization of 12 months may be granted for vulvar cancer when all of the following criteria are met:

1. The requested drug will be used as concurrent chemoradiation in combination with mitomycin.
2. The requested drug will be used if cisplatin is unavailable.

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

III. REFERENCES

1. Xeloda [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
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3. Clinical Pharmacology powered by ClinicalKey [database online]. Tampa, FL. Elsevier; https://www.clinicalkey.com/pharmacology/ [available with subscription]. Accessed July 6, 2023.
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5. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 6, 2023.
6. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 6, 2023.
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PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**WEIGHT LOSS MANAGEMENT**
BRAND NAME (generic)	**XENICAL (orlistat)**

Type: Initial Prior Authorization with Quantity Limit

POLICY

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. Xenical is indicated for obese patients with an initial body mass index (BMI) greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug will be used with a reduced calorie diet and increased physical activity for obesity management
  AND
  - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
    AND
    - The patient has a body mass index (BMI) greater than or equal to 30 kg/m^2. [Documentation is required for approval.]

    OR
    - The patient has a body mass index (BMI) greater than or equal to 27 kg/m^2. [Documentation is required for approval.]
      AND
      - The patient has at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). [Documentation is required for approval.]

  OR
  - The patient has completed at least 6 months of therapy with the requested drug
    AND
    - The patient has lost at least 5 percent of baseline bodyweight OR the patient has continued to maintain their initial 5 percent weight loss. [Documentation is required for approval.]
      AND
      - Documentation of the patient's weight prior to starting Xenical therapy and the patient's current weight after Xenical therapy, including the date the weights were taken, has been submitted to CVS Health

Quantity Limits apply.
90 capsules per 25 days* or 270 capsules per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 250-C: Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC; November 2022.

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed May 10, 2023.
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4. Jensen MD, Ryan DH, Apovian DM, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society. *Circulation*. 2014;129(suppl 2):S102-S138.
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