Utilization Management Policy Name: Saxenda® & Wegovy™ – NC Standard

Restricted Product(s):

- Saxenda® (liraglutide)
- Wegovy™ (semaglutide)

FDA Approved Use:

Saxenda & Wegovy:

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

Saxenda:

- As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with body weight above 60kg and an initial BMI corresponding to ≥30 kg/m^2 for adults (obese) by international cut-offs.

Criteria for Approval of Restricted Product(s):

Initial Coverage Criteria

1. The patient has taken the medication for less than 18 weeks (NOTE: for members who are new to the plan that meet initial coverage requirements with greater than 18 weeks of therapy, use the continuation criteria); **AND**
2. The patient is 18 years of age or older; **AND**
    a. The patient has one of following:
        i. A diagnosis of obesity and a BMI ≥ 30 kg/m^2; **OR**
        ii. A diagnosis of obesity and a BMI ≥ 25 kg/m^2 and the patient is of South Asian, Southeast Asian, or East Asian descent; **OR**
        iii. The patient has a documented BMI ≥ 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g. diabetes, dyslipidemia, coronary artery disease); **OR**
3. The patient is 12 – 17 years of age; **AND**
    a. The request is for Saxenda (liraglutide); **AND**
    b. The patient has a body weight of > 60 kg; **AND**
    c. The patient has a diagnosis of obesity and a BMI corresponding to ≥30 kg/m^2 for adults by international cut-offs; **AND**
4. The requested medication will NOT be used concurrently with another GLP-1 receptor agonist medication; **AND**
5. The requested medication will NOT be used concurrently with insulin; **AND**
6. The requested medication will NOT be used concurrently with another weight loss medication; **AND**

7. The patient has NOT had a failed attempt at weight loss with a different weight loss medication in the past 12 months; **OR**
    a. The prescriber has provided sufficient information to show how an additional trial with the requested weight loss medication would now be successful **[clinical rationale included]; AND**
8. The provider has addressed the requirement for lifestyle modifications (calorie restrictions and increased activity) while taking the requested medication; **AND**
9. The patient was unable to achieve acceptable weight loss through lifestyle modifications (defined as a 1lb per week weight loss through calorie restriction, increased activity, and behavioral modifications in a 6 month period); **OR**
    a. The patient has a weight-related comorbidity/risk factor/complication (e.g. diabetes, dyslipidemia, coronary artery disease) that warrants medication interventions immediately; **AND**
10. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies.

Duration of Approval: 18 weeks

Continuation Coverage Criteria

1. The patient was approved through Blue Cross NC initial coverage criteria; **OR**
2. The patient is new to the plan and meets initial coverage requirements listed above, and has taken the medication greater than 18 weeks; **AND**
3. The patient is 18 years of age or older; **AND**
    a. The patient has achieved and maintained a weight loss of ≥4% from baseline (prior to the initiation of requested medication); **OR**
4. The patient is 12 – 17 years of age; **AND**
    a. The request is for Saxenda (liraglutide); **AND**
    b. The patient has achieved and maintained a weight loss of ≥ 1% from baseline (prior to the initiation of requested medication).

Duration of Approval: 365 days (1 year)

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	**Quantity Limit**
Saxenda (liraglutide) 6 mg/mL, 3 mL/pen	5 pens per 30 days
Wegovy (semaglutide) 0.25 mg/0.5 mL, 0.5 mL/pen	4 pens per 180 days
Wegovy (semaglutide) 0.5 mg/0.5 mL, 0.5 mL/pen	4 pens per 180 days
Wegovy (semaglutide) 1 mg/0.5 mL, 0.5 mL/pen	4 pens per 180 days

Wegovy (semaglutide) 1.7 mg/0.75 mL, 0.75 mL/pen	8 pens per 180 days
Wegovy (semaglutide) 2.4 mg/0.75 mL, 0.75 mL/pen	4 pens per 28 days

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 30 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

References: all information referenced is from FDA package insert unless otherwise noted below.

Misra, Anoop. "Ethnic-Specific Criteria for Classification of Body Mass Index: A Perspective for Asian Indians and American Diabetes Association Position Statement." *Diabetes technology & therapeutics* vol. 17,9 (2015): 667-71. doi:10.1089/dia.2015.0007

Policy Implementation/Update Information:

December 2021: Criteria update: Authorizations for titration purposes updated to 30 day period.
July 2021: Criteria change: Combined Enhanced with Enh/NR criteria; Name changed to NC Standard (Enhanced formulary no longer required to step through Qsymia); Wegovy added to policy.
April 2021: Criteria change: Applied this criterion to Essential formulary. (Essential formulary no longer required to step through Qsymia).
Dec 2020: Criteria update: Added expanded indication for pediatric patients ≥ 12 years of age.
April 2019: Policy originated for Net Results formulary