Utilization Management Policy Name: GLP-1 Agonists – NC Standard

Restricted Product(s):

- Adlyxin (lixisenatide)
- Bydureon (exenatide extended-release)
- Bydureon BCise (exenatide extended release)
- Byetta (exenatide)
- Ozempic (semaglutide)
- Rybelsus (semaglutide)
- Trulicity (dulaglutide)
- Victoza (liraglutide)

FDA Approved Use:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease (Victoza only)

Criteria for Approval of Restricted Product(s):

1. The patient has a diagnosis of type 2 diabetes mellitus; **AND**
    a. The patient's medication history includes one or more of the following: an agent containing metformin, sulfonylurea or insulin in the past 90 days; **OR**
    b. The patient has tried and had an inadequate response, has an intolerance, or hypersensitivity to one of the following agents: metformin, sulfonylurea, or an insulin; **OR**
    c. The patient has a FDA labeled contraindication to ALL of the following agents: metformin, sulfonylureas, and insulins; **OR**
2. The prescriber states the patient is currently being treated with the requested agent within the past 90 days AND is at risk if therapy is changed; **AND**
3. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

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

Medication	Quantity per Day (unless specified)
Adlyxin® (lixisenatide) 50 mcg/mL prefilled pen	2 pens every 28 days
Adlyxin (lixisenatide) 100 mcg/mL prefilled pen	2 pens every 28 days
Bydureon® (exenatide ER) 2 mg/vial/pen	1 carton (4 trays/4 doses) per 28 days
Bydureon BCis™ (exenatide ER) 2 mg/pen	4 pens every 28 days
Byetta® (exenatide) 5 mcg/dose prefilled pen	1 prefilled pen (60 doses) every 30 days
Byetta (exenatide) 10 mcg/dose prefilled pen	1 prefilled pen (60 doses) every 30 days
Ozempic (semaglutide) 0.25 mg or 0.5mg per dose (2mg/1.5mL) 1.5 mL, 1 pen	1 pen per 28 days
Ozempic (semaglutide) 1 mg per dose (2mg/1.5 mL) 3 mL, 2 pens	2 pens per 28 days
Rybelsus® (semaglutide) 3mg tablet	1 tablet
Rybelsus® (semaglutide) 7mg tablet	1 tablet
Rybelsus® (semaglutide) 14mg tablet	1 tablet
Trulicity® (dulaglutide) 0.75 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Trulicity (dulaglutide) 1.5 mg / 0.5 mL syringe and pens	4 pens or syringes every 28 days
Victoza® (liraglutide) 18 mg/3 mL pen; 2 pen package	3 pens every 30 days
Victoza (liraglutide) 18 mg/3 mL pen; 3 pen package	3 pens every 30 days

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 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).

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; **AND**
b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

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

Policy Implementation/Update Information:

October 2020: Original utilization management criteria issued.

Non-Discrimination and Accessibility Notice

Discrimination is Against the Law

- Blue Cross and Blue Shield of North Carolina ("Blue Cross NC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.
- Blue Cross NC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

  Blue Cross NC:

  - Provides free aids and services to people with disabilities to communicate effectively with us, such as:
    - Qualified interpreters
    - Written information in other formats (large print, audio, accessible electronic formats, other formats)
  - Provides free language services to people whose primary language is not English, such as:
    - Qualified interpreters
    - Information written in other languages
- If you need these services, contact Customer Service **1-888-206-4697**, TTY and TDD, call **1-800-442-7028**.

- If you believe that Blue Cross NC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
  - Blue Cross NC, PO Box 2291, Durham, NC 27702, Attention: Civil Rights Coordinator- Privacy, Ethics & Corporate Policy Office, Telephone **919-765-1663**, Fax **919-287-5613**, TTY **1-888-291-1783** civilrightscoordinator@bcbsnc.com
- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

- This Notice and/or attachments may have important information about your application or coverage through Blue Cross NC. Look for key dates. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call Customer Service **1-888-206-4697**.

ATTENTION: If you speak another language, language assistance services, free of charge, are available to you. Call 1-888-206-4697 (TTY: 1-800-442-7028).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-206-4697 (TTY: 1-800-442-7028).

注意：如果您講廣東話或普通話， 您可以免費獲得語言援助服務。請致電 1-888-206-4697 (TTY：1-800-442-7028）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-888-206-4697 (TTY: 1-800-442-7028).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.
1-888-206-4697 (TTY: 1- 800-442-7028)번으로 전화해 주십시오.

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-888-206-4697 (ATS : 1-800-442-7028).

ملحوظة: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم
1-888-206-4697. المبرقة الكاتبة: 1-800-442-7028.

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau
1-888-206-4697 (TTY: 1-800-442-7028).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-206-4697 (телетайп: 1-800-442-7028).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-888-206-4697 (TTY: 1-800-442-7028).

સુચના: જો તમે ગુજરાતી બોલતા હો, તો નિ:સુલ્કુ ભાષા સહાય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો
1-888-206-4697 (TTY: 1-800-442-7028).

ចំណាំ៖ ប្រសិនបើលោកអ្នកនិយាយជាភាសាខ្មែរ សេវាកម្មជំនួយផ្នែកភាសាមានផ្តល់ជូនសម្រាប់លោកអ្នកដោយមិនគិតថ្លៃ។ សូមទំនាក់ទំនងតាមរយៈលេខ៖ 1-888-206-4697 (TTY: 1-800-442-7028)។

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-888-206-4697 (TTY: 1-800-442-7028).

ध्यान दें: यदि आप हिन्दी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। 1-888-206-4697 (TTY: 1-800-442-7028) पर कॉल करें।

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