Utilization Management Policy Name: Akynzeo® - NC Standard

Restricted Product(s):

- Akynzeo® (netupitant/palonosetron) tablets

FDA Approved Use:

- For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Criteria for Approval of Restricted Product(s):

1. The patient is ≥18 years of age; **AND**
2. Akynzeo is being prescribed for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy; **AND**
    a. There is documented use of an emetogenic cancer chemotherapy agent listed in the most recent NCCN guidelines (refer to guidelines on pages 3-6); **AND**
    b. **If prescribing highly and/or moderately emetogenic intravenous chemotherapy and a neurokinin-1 (NK1) antagonist,**
        i. The patient has experienced a therapeutic failure or inadequate response to generic oral ondansetron, generic oral granisetron, or generic oral aprepitant; **OR**
        ii. The patient has a contraindication to generic oral ondansetron, generic oral granisetron, or generic oral aprepitant; **AND**
        iii. The patient has experienced a therapeutic failure or inadequate response to oral rolapitant (Varubi); **OR**
        iv. The patient has a contraindication to oral rolapitant (Varubi); **OR**
    b. **If prescribing low and/or minimal emetogenic intravenous chemotherapy and/or emetogenic oral chemotherapy,**
        i. The patient has experienced a therapeutic failure or inadequate response to generic oral ondansetron or generic oral granisetron; **OR**
        ii. The patient has a contraindication to generic oral ondansetron or generic oral granisetron; **AND**
        iii. The patient has experienced a therapeutic failure or inadequate response to oral rolapitant (Varubi); **OR**
        iv. The patient has a contraindication to oral rolapitant (Varubi); **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 30 Days
Akynzeo (netupitant/palonosetron) 300 mg netupitant/0.5 mg palonosetron capsule	2 capsules

Quantity Limit Exception Criteria:

1. The patient has cancer chemotherapy related nausea and vomiting and will be receiving chemotherapy more than 7 days per month **OR**
2. The patient has delayed emesis in highly emetogenic chemotherapy; **OR**
3. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
4. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
5. 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**
6. 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).

Duration of Approval: 365 days (1 year)

***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.

NCCN Clinical Practice Guidelines in Oncology. Antiemesis Version 3.2018. http://www.nccn.org/

Nausea and vomiting of pregnancy. ACOG Practice Bullentin No. 189. American College of Obetetricians and Gynecologists. Obstet Gynecol 2018; 131:e15-30.

Policy Implementation/Update Information:

January 2020: Criteria change: Added requirement of a therapeutic failure/inadequate response/contraindication to Varubi.
January 2019: Update to Emetogenic Potential of Intravenous and Oral Antineoplastic Agents Table; Review and reformat criteria
December 2018: Update to Emetogenic Potential of Intravenous and Oral Antineoplastic Agents Table
October 2016: Reviewed for ASO Net Results and Essential formularies. Removed verbiage in regard to restricted access for Enhanced and Basic Open formularies. Non-formulary verbiage added.
January 2016: 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.

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- 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**.

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  - 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).

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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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