# North Dakota Medicaid
# Drug Utilization Review Board Meeting
# September 6, 2023
# Conference Room 210/212

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# Meeting Notice

## North Dakota Medicaid Drug Use Review Board

Wednesday, September 6th, 2023
1 to 4 p.m. Central Time

## In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 E. Boulevard Ave., Bismarck

## Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 617 220 993#

### Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Unwinding, Humira biosimilars, RSV
    - Financial Report: Budget, Top Drugs
    - Clinical Report:
        - Prior authorization update
        - Annual PDL Review Criteria Updates for Gout, Chronic Kidney Disease, Heart Failure, Long-Acting Opioid Analgesics, Opioid Use Disorder, Clostridioides difficile-associated diarrhea (CDAD), Medications over $3000
    - Retrospective DUR report
5. Unfinished Business
    - Update to Hyperparathyroidism (Sensipar)
6. New business
    - First Review of Diuretics (triamterene)
    - First Review of Menopause (Veozah)
    - Review of retrospective DUR criteria recommendations
7. Announcements
    - Next Meeting (December 6th, 2023)
8. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY) or gervingashley@nd.gov.

**Meeting Minutes**
**North Dakota Medicaid Drug Use Review (DUR) Board**
**Meeting Date:** June 7th, 2023
**Time and Location:** 1:00 pm CST in Bismarck, North Dakota

**Board Members:**
*Present:* Andrea Honeyman, Gabriela Balf, Amy Werremeyer, Laura Kroetsch, Kevin Martian, Kristen Peterson, Josh Askvig, Stephanie Antony, Jennifer Iverson
*Absent:* Tanya Schmidt, Kathleen Traylor
*Quorum Present:* Yes

**Medicaid Pharmacy Department:**
*Present:* Brendan Joyce, LeNeika Roehrich, Alexi Murphy
*Absent:* Jeff Hostetter

**Call to Order:**
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:02 pm CST. with pro tem Presiding Officer K. Martian presiding, and DUR Board Coordinator, C. Stauter recording minutes. In Presiding Officer T. Schmidt's absence, K. Martian served as Presiding Officer pro tem.

**Approval of Meeting Minutes:**
The minutes of the March 1, 2023, meeting were approved as distributed.

**Reports:**
*Administrative Report***:** *Legislative Update* provided by A. Murphy
A. Murphy shared with the Board all changes made affecting the DUR Board from Senate Bill 2156, effective August 1, 2023. These changes can be found in the handout.

*Administrative Report***:** *Robert's Rules of Order* provided by A. Murphy
A. Murphy shared with the Board all changes made affecting the DUR Board elections, debate, minutes, old business, first and second reviews, and adjournment. These changes can be found in the handout.

*Administrative Report***:** *Member Update* provided by A. Murphy
A. Murphy introduced the new Board Member S. Antony. L. Morgan introduced the new DUR Board Coordinator C. Stauter.

*Financial Report: Budget* provided by A. Murphy
A. Murphy shared with the Board the history of ND Medicaid pharmacy spending and rebates. These specifics can be found in the handout.

*Financial Report: Top Drugs* provided by L. Morgan
L. Morgan presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

*Clinical Report: Prior Authorization Update* provided by A. Murphy
A. Murphy shared with the Board new medications requiring prior authorizations. This list can be found in the handout.

*Clinical Report: Criteria Update*
*Update to Hepatitis C* provided by A. Murphy
A. Murphy discussed the changes to the hepatitis C section to the PDL. L. Morgan presented the updated prior authorization form and consent forms for discussion. These changes can be found in the handout.

*Update to Chronic Kidney Disease (Filspari)* provided by L. Morgan

L. Morgan discussed the changes to the chronic kidney disease section to the PDL for discussion. These changes can be found in the handout.

*Retrospective Drug Utilization Review (RDUR) Report***:** C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

**Special Orders:**
*Presiding Officer and Vice-Presiding Officer Elections*
Nomination by J. Askvig for T. Schmidt as Presiding Officer, motion was seconded, **motion carried.**
Nomination by J. Askvig for A. Honeyman as Vice-Presiding Officer, motion was seconded, **motion carried.**

**New Business:**
L. Morgan presented an overview of hyperparathyroidism, influenza, neuromyelitis optica spectrum disorder, and urea cycle agents. The presented material can be found in the handout.

RDUR criteria recommendations were reviewed. The presented material can be found in the handout.

*Second Review of Hyperparathyroidism*:
*Motion:* Moved by K. Martian for the Department to adopt criteria as distributed for hyperparathyroidism, motion was seconded. **Motion carried.**

*Second Review of Influenza:*
*Motion:* Moved by K. Martian for the Department to adopt criteria as distributed for influenza, motion was seconded. **Motion carried.**

*Second Review of Neuromyelitis Optica Spectrum Disorder:*
*Motion:* Moved by J. Askvig for the Department to adopt criteria as distributed for neuromyelitis optica spectrum disorder, motion was seconded. **Motion carried.**

*Second Review of Urea Cycle Agents:*
*Motion:* Moved by K. Martian for the Department to adopt criteria as distributed for urea cycle agents, motion was seconded. **Motion carried.**

*Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:*
*Motion:* Moved by J. Askvig to approve the RDUR criteria, motion was seconded. **Motion carried.**

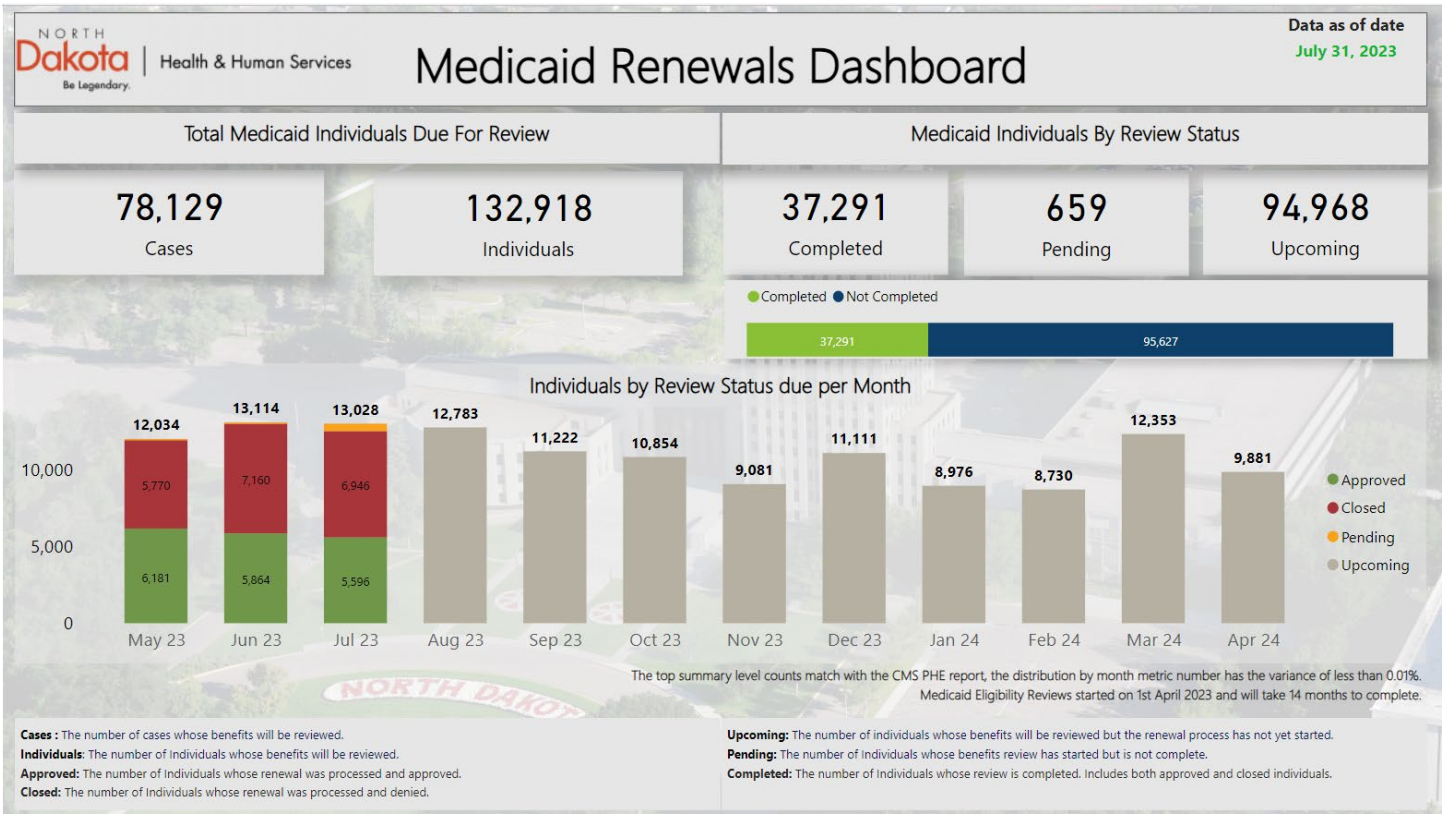
**Announcements:**
Next meeting is September 6th, 2023.

**Adjournment:**
Meeting adjourned by K. Martian at 2:25 pm CST.

**Date of Minutes Approval:**
**Minutes submitted by:** Claire Stauter, Kepro

**Unwinding:**

https://www.hhs.nd.gov/medicaid/data > Medicaid Renewals:



**RSV:**

ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics

Advisory Committee on Immunization Practices (ACIP) Recommendations:

On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended use of nirsevimab as indicated in its FDA package insert:

- Infants aged <8 months born during or entering their first Respiratory Syncytial Virus (RSV) season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg).
- Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg).

The ACIP also voted for inclusion of nirsevimab in the Vaccines for Children (VFC) program.

American Academy of Pediatrics (AAP) Recommendations

American Academy of Pediatrics Recommendations for the 2023–2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season:

- If nirsevimab is administered, palivizumab should not be administered later that season.
- If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.
- If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

No recommendations from AAP/ACIP for use with monoclonal antibody prophylaxis:

Vaccine for respiratory syncytial virus (RSV) : Abrysvo

- For protection of infants from the virus from birth to 6 months of age to be given between weeks 32 and 36 of pregnancy (Approved August 2023)
- For protection of people aged 60 years and older (Approved May 2023)

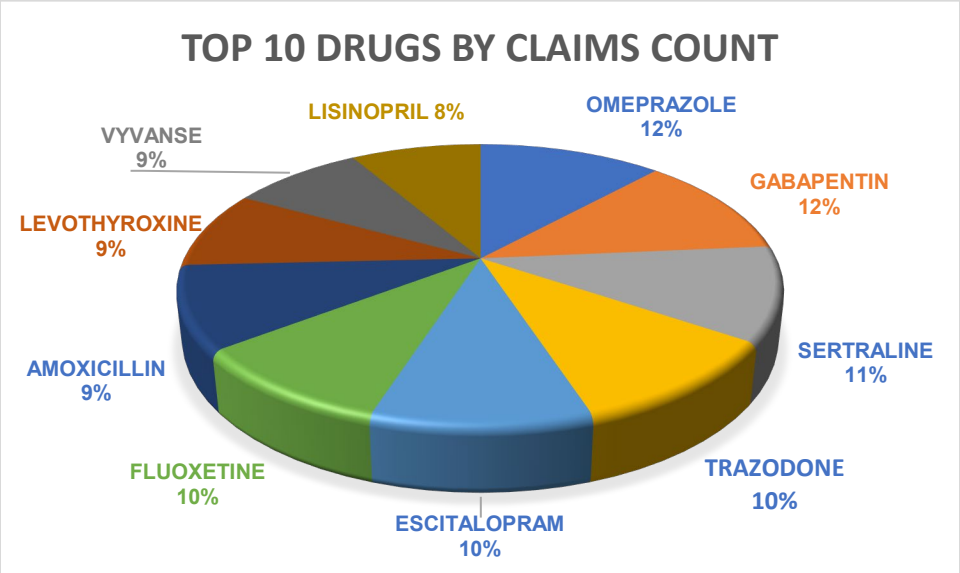
North Dakota Medicaid Plan

- Beyfortus (nirsevimab) is expected to be available in the U.S. ahead of the upcoming 2023-2024 RSV season.
- The North Dakota Department of Health and Human Services Immunization Unit supplies free vaccines for children who are eligible for the Vaccines for Children (VFC) program.
- ND Medicaid will not provide RSV prophylaxis (Synagis or Beyfortus) coverage for infants eligible to receive Beyfortus through the VFC program.
- Continue to monitor AAP/ACIP recommendations for updates regarding use of Abrysvo.

## Top 25 Drugs Based on Number of Claims from 04/01/2023 – 06/30/2023

| Drug | Claims | Claims Cost | Patients | Cost / Claim | % Total Claims | Dif. |
|---|---|---|---|---|---|---|
| 1. OMEPRAZOLE | 4,780 | $61,334.67 | 2,452 | $12.83 | 1.8% | NC |
| 2. GABAPENTIN | 4,756 | $70,617.96 | 2,047 | $14.85 | 1.8% | NC |
| 3. SERTRALINE HCL | 4,438 | $60,082.07 | 2,548 | $13.54 | 1.7% | NC |
| 4. TRAZODONE HCL | 4,034 | $54,266.42 | 2,068 | $13.45 | 1.5% | NC |
| 5. ESCITALOPRAM | 4,029 | $54,166.97 | 2,369 | $13.44 | 1.5% | ↑1 |
| 6. FLUOXETINE HCL | 3,967 | $52,665.49 | 2,178 | $13.28 | 1.5% | ↑1 |
| 7. AMOXICILLIN | 3,745 | $53,781.88 | 3,529 | $14.36 | 1.4% | ↓2 |
| 8. LEVOTHYROXINE | 3,558 | $56,732.96 | 1,904 | $15.95 | 1.3% | ↑1 |
| 9. VYVANSE | 3,445 | $959,714.37 | 1,456 | $278.58 | 1.3% | ↓1 |
| 10. LISINOPRIL | 3,408 | $44,206.91 | 2,082 | $12.97 | 1.3% | NC |
| 11. ATORVASTATIN | 3,311 | $46,943.20 | 1,978 | $14.18 | 1.2% | NC |
| 12. BUPROPION XL | 3,269 | $55,023.40 | 1,806 | $16.83 | 1.2% | NC |
| 13. PANTOPRAZOLE | 3,142 | $43,799.50 | 1,565 | $13.94 | 1.2% | NC |
| 14. VENTOLIN HFA | 3,049 | $195,110.70 | 3,023 | $63.99 | 1.1% | ↑9 |
| 15. HYDROCODONE-APAP | 2,812 | $40,883.63 | 1,788 | $14.54 | 1.0% | ↓1 |
| 16. CYCLOBENZAPRINE | 2,730 | $31,639.66 | 1,737 | $11.59 | 1.0% | ↓1 |
| 17. DULOXETINE HCL | 2,722 | $44,150.27 | 1,448 | $16.22 | 1.0% | ↓1 |
| 18. CLONIDINE HCL | 2,688 | $32,921.20 | 1,355 | $12.25 | 1.0% | NC |
| 19. HYDROXYZINE HCL | 2,653 | $35,848.70 | 1,667 | $13.51 | 1.0% | ↑2 |
| 20. PREDNISONE | 2,623 | $31,457.70 | 2,148 | $11.99 | 1.0% | NC |
| 21. LAMOTRIGINE | 2,597 | $36,996.03 | 1,116 | $14.25 | 1.0% | ↑3 |
| 22. AMOXICILLIN-CLAV | 2,487 | $44,172.95 | 2,336 | $17.76 | 0.9% | ↓5 |
| 23. BUP-NALOXONE | 2,472 | $105,145.74 | 667 | $42.53 | 0.9% | ↓1 |
| 24. BUSPIRONE HCL | 2,371 | $36,045.20 | 1,329 | $15.20 | 0.9% | ↑1 |
| 25. AMLODIPINE | 2,350 | $30,116.93 | 1,363 | $12.82 | 0.9% | ↑4 |

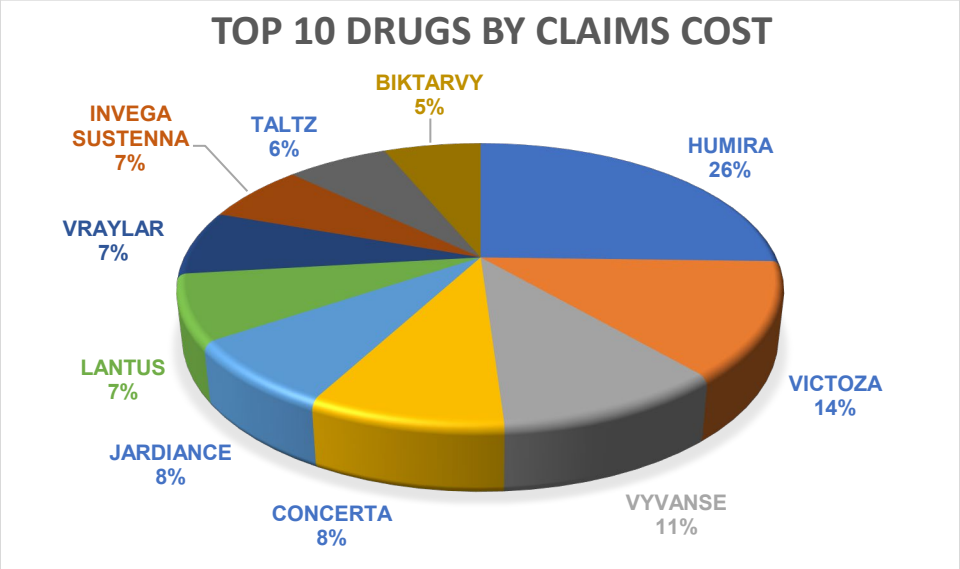
| **Total Claims** | **268,762** |
|---|---|



## Top 25 Drugs Based on Total Claims Cost from 04/01/2023 – 06/30/2023

| Drug | Claims | Claims Cost | Patients | Cost / Patient | % Total Cost | Dif. |
|---|---|---|---|---|---|---|
| 1. HUMIRA | 298 | $2,369,800.15 | 129 | $36,805.07 | 6.8% | NC |
| 2. VICTOZA | 1,440 | $1,280,526.06 | 722 | $3,437.17 | 3.7% | NC |
| 3. VYVANSE | 3,445 | $959,714.37 | 1,456 | $659.14 | 2.8% | NC |
| 4. CONCERTA | 2,021 | $742,939.96 | 878 | $846.17 | 2.1% | NC |
| 5. JARDIANCE | 1,054 | $719,714.34 | 562 | $1,280.63 | 2.1% | ↑1 |
| 6. LANTUS SOLOSTAR | 1,315 | $674,274.62 | 815 | $827.33 | 1.9% | ↓1 |
| 7. VRAYLAR | 627 | $606,021.84 | 267 | $2,269.74 | 1.7% | ↑5 |
| 8. INVEGA SUSTENNA | 234 | $603,537.30 | 94 | $6,420.61 | 1.7% | ↓1 |
| 9. TALTZ | 90 | $563,834.38 | 37 | $15,238.77 | 1.6% | ↓1 |
| 10. BIKTARVY | 246 | $474,504.98 | 121 | $3,921.53 | 1.4% | NC |
| 11. STELARA | 19 | $449,263.66 | 16 | $28,078.98 | 1.3% | ↓2 |
| 12. ADDERALL XR | 2,210 | $407,926.75 | 972 | $419.68 | 1.2% | ↑2 |
| 13. MAVYRET | 33 | $404,248.01 | 21 | $19,249.91 | 1.2% | ↓3 |
| 14. ELIQUIS | 706 | $398,791.14 | 341 | $1,169.48 | 1.1% | ↓1 |
| 15. TRIKAFTA | 19 | $396,954.88 | 8 | $49,619.36 | 1.1% | ↑4 |
| 16. SYMBICORT | 1,100 | $386,516.13 | 640 | $603.93 | 1.1% | NC |
| 17. NORDITROPIN | 85 | $359,585.00 | 40 | $8,989.63 | 1.0% | ↑4 |
| 18. ADVAIR DISKUS | 914 | $342,726.20 | 506 | $677.32 | 1.0% | ↓1 |
| 19. NOVOLOG FLEXPEN | 452 | $340,017.54 | 287 | $1,184.73 | 1.0% | ↓1 |
| 20. ABILIFY MAINTENA | 121 | $288,510.77 | 49 | $5,887.97 | 0.8% | NC |
| 21. DUPIXENT PEN | 88 | $281,760.55 | 38 | $7,414.75 | 0.8% | ↑1 |
| 22. SOFO-VELPATASVIR | 35 | $273,263.30 | 15 | $18,217.55 | 0.8% | ↑17 |
| 23. XIFAXAN | 93 | $251,608.20 | 45 | $5,591.29 | 0.7% | NC |
| 24. SUBLOCADE | 129 | $249,351.84 | 60 | $4,155.86 | 0.7% | ↑10 |
| 25. LEVEMIR FLEXPEN | 403 | $248,682.67 | 251 | $990.77 | 0.7% | ↑2 |

| **Total Claims Cost** | **$34,870,800.35** |
|---|---|



## Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2023 – 06/30/2023

| Therapeutic Class Description | Claims | Claims Cost | Patients | Cost/Claim | % Total Claims | Dif. |
|---|---|---|---|---|---|---|
| 1. ANTIDEPRESSANTS | 30,485 | $660,732.16 | 13,096 | $21.67 | 11.3% | NC |
| 2. ANTICONVULSANTS | 13,862 | $551,732.40 | 5,065 | $39.80 | 5.2% | NC |
| 3. ANTIPSYCHOTICS | 9,672 | $2,433,160.77 | 3,922 | $251.57 | 3.6% | NC |
| 4. PPI'S | 8,322 | $157,833.32 | 4,160 | $18.97 | 3.1% | NC |
| 5. ANXIOLYTICS, SEDATIVES, HYPNOTICS | 7,696 | $111,802.75 | 4,041 | $14.53 | 2.9% | NC |
| 6. AMPHETAMINES | 7,175 | $1,423,056.31 | 3,065 | $198.34 | 2.7% | NC |
| 7. OPIATE AGONISTS | 6,865 | $108,986.71 | 3,680 | $15.88 | 2.6% | ↑1 |
| 8. PENICILLIN ANTIBIOTICS | 6,564 | $103,267.77 | 5,932 | $15.73 | 2.4% | ↓1 |
| 9. NSAIDS | 6,416 | $89,525.82 | 4,314 | $13.95 | 2.4% | NC |
| 10. STATINS | 5,910 | $85,875.84 | 3,491 | $14.53 | 2.2% | ↑1 |
| 11. RESP/CNS STIMULANTS | 5,723 | $957,880.83 | 2,250 | $167.37 | 2.1% | ↓1 |
| 12. BETA BLOCKING AGENTS | 5,566 | $99,228.03 | 3,125 | $17.83 | 2.1% | NC |
| 13. ADRENALS | 4,374 | $59,273.88 | 3,505 | $13.55 | 1.6% | NC |
| 14. BETA AGONISTS | 4,333 | $261,176.56 | 3,970 | $60.28 | 1.6% | NC |
| 15. ACE INHIBITORS | 4,238 | $67,143.00 | 2,567 | $15.84 | 1.6% | NC |

## Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2023 – 06/30/2023

| Therapeutic Class Description | Claims | Claims Cost | Patients | Cost/Patient | % Total Cost | Dif. |
|---|---|---|---|---|---|---|
| 1. DMARDS | 652 | $3,867,842.27 | 272 | $14,220.01 | 11.1% | NC |
| 2. ANTIPSYCHOTICS | 9,672 | $2,433,160.77 | 3,922 | $620.39 | 7.0% | NC |
| 3. SKIN AGENTS | 702 | $2,061,210.88 | 420 | $4,907.64 | 5.9% | NC |
| 4. INSULINS | 3,609 | $1,902,722.57 | 1,451 | $1,311.32 | 5.5% | NC |
| 5. INCRETIN MIMETICS | 1,646 | $1,461,430.59 | 756 | $1,933.11 | 4.2% | ↑2 |
| 6. ANTINEOPLASTICS | 634 | $1,436,618.88 | 267 | $5,380.60 | 4.1% | ↓1 |
| 7. AMPHETAMINES | 7,175 | $1,423,056.31 | 3,065 | $464.29 | 4.1% | ↓1 |
| 8. CORTICOSTEROID (RESP) | 3,705 | $1,102,822.73 | 2,242 | $491.89 | 3.2% | ↑1 |
| 9. SGLT-2 INHIBITORS | 1,470 | $978,569.30 | 782 | $1,251.37 | 2.8% | ↑2 |
| 10. RESP/CNS STIMULANTS | 5,723 | $957,880.83 | 2,250 | $425.72 | 2.7% | NC |
| 11. ANTIRETROVIRALS | 736 | $946,848.72 | 291 | $3,253.78 | 2.7% | ↓3 |
| 12. HCV ANTIVIRALS | 68 | $677,511.31 | 36 | $18,819.76 | 1.9% | ↑1 |
| 13. ANTIDEPRESSANTS | 30,485 | $660,732.16 | 13,096 | $50.45 | 1.9% | ↓1 |
| 14. IMMUNOMODULATORY | 88 | $586,616.81 | 36 | $16,294.91 | 1.7% | ↑2 |
| 15. ANTICOAGULANTS | 1,508 | $558,295.57 | 649 | $860.24 | 1.6% | NC |

| PA / PDL Update | PA Status | Class |
|---|---|---|
| Fabior (tazarotene) foam | PA | Acne |
| Carac (fluorouracil) cream | PA | Actinic Keratosis |
| Suflave | PA | Bowel Prep Agents |
| Rinvoq | PA | Crohn's |
| alosetron | PA | Diarrhea - IBS |
| Miebo | PA | Dry Eye Disease |
| Olumiant | PA | Eczema/Atopic Dermatitis |
| Menest | PA | Estrogens |
| travoprost | PA | Glaucoma |
| apraclonidine | PA | Glaucoma |
| tafluprost | PA | Glaucoma |
| Sogroya | PA | Growth Hormone |
| Rayaldee ER | PA | Hyperparathyroidism |
| doxercalciferol | PA | Hyperparathyroidism |
| Xofluza | PA | Influenza |
| Zavzpret | PA | Migraine |
| Fosamax D | PA | Osteoporosis |
| Elepsia XR | PA | Preferred Dosage Forms |
| Spritam | PA | Preferred Dosage Forms |
| Sympazan | PA | Preferred Dosage Forms |
| olanzapine/fluoxetine | PA | Preferred Dosage Forms |
| Cotempla XR - ODT | PA | Preferred Dosage Forms |
| amphetamine ER Suspension | PA | Preferred Dosage Forms |
| Pexeva | PA | Preferred Dosage Forms |
| Liqrev | PA | Pulmonary Hypertension |
| Pandel | PA | Topical Steroids |
| Fluocinonide-E cream | PA | Topical Steroids |
| Olpruva | PA | Urea Cycle Disorders |
| Symproic | remove PA | Constipation (Opioid-Induced) |
| Simponi | remove PA | Cytokine Modulators |
| Nivestym | remove PA | Hematopoietic, Colony Stimulating Factor |
| Releuko | remove PA | Hematopoietic, Colony Stimulating Factor |
| Nexletol | remove PA | Lipid-Lowering Agents |
| Nexlizet | remove PA | Lipid-Lowering Agents |
| gatifloxacin eye drops | remove PA | Ophthalmic - Antiinfectives |
| Airduo Respiclick | remove PA | Steroid/LABA combination inhalers |
| Tlando | remove PA | Testosterone |
| clocortolone cream | remove PA | Topical Steroids |
| halobetasol ointment | remove PA | Topical Steroids |
| desoximetasone cream | remove PA | Topical Steroids |

## Chronic Kidney Disease

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*
- If member is on renal dialysis, Medicare eligibility must be ruled out.

*Filspari Only*
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria ≥ 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor

*Inpefa Only:*
- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out.
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)

*Kerendia Only*
- The member must have history of diabetes
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m2 AND one of the following (1 or 2):
  1. Urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. Albuminuria ≥ 300 mg/day

*Korsuva Only*
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

*Tarpeyo Only*
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 6-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - Prednisone or methylprednisolone

*<u>Renewal Criteria - Approval Duration:</u> 12 months*

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - *Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g
  - *Kerendia Only*: albuminuria <1 gram/day or UACR < 1.5 g/g

**References:**


1. *Rossing, Peter, et al. "KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease." Kidney international 102.5 (2022): S1-S127.*
2. *de Boer, Ian H., et al. "Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO)." Diabetes care 45.12 (2022): 3075-3090.*

## Heart Failure

*First Line Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred* | INPEFA (sotagliflozin) |
| ARBs (angiotensin receptor blockers) - *all oral agents preferred* | |
| Beta blockers - *all oral agents preferred* | |
| ENTRESTO (sacubitril/valsartan) | |
| FARXIGA (dapagliflozin) | |
| JARDIANCE (empagliflozin) | |

*Second Line Agents*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CORLANOR (ivabradine) | |
| VERQUVO (vericiguat) | |

### *Electronic Diagnosis Verification*

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.
  - Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - Documentation of a recent hospitalization or need for IV diuretics within the past 6 months must be provided with request.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

# Opioid Analgesics

## Opioid Analgesics – Long Acting

### Partial Agonist/Antagonist Opioids

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BELBUCA (buprenorphine) | buprenorphine patches |
| Butorphanol | |
| BUTRANS (buprenorphine) PATCHES<br>- *Brand Required* | |

### Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NUCYNTA ER (tapentadol) | CONZIP (tramadol ER) CAPSULES |
| OXYCONTIN (oxycodone) – *Brand Required* | hydrocodone ER tablets |
| tramadol ER Tablets | HYSINGLA ER (hydrocodone) |
| | levorphanol |
| | methadone |
| | MORPHABOND ER (morphine) |
| | tramadol ER capsules |
| | XTAMPZA ER (oxycodone) |

### Full Agonist Opioids Without Abuse Deterrent Formulations

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr,<br>75 mcg/hr, 100 mcg/hr | fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr |
| morphine ER tablets | hydrocodone ER capsules |
| | hydromorphone ER tablets |
| | morphine ER capsules |
| | MS CONTIN (morphine) |
| | oxycodone ER |
| | oxymorphone ER tablets |

*Prior Authorization Criteria*

Prior Authorization Form – Opioid Analgesics

*Initial Criteria - Approval Duration: 12 months*

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to Narcan and has been counseled on overdose risk
  - The member resides in a facility with skilled nursing care
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy
  - The member must have received opioid therapy during hospitalization requiring post discharge maintenance or tapering
  - Both of the following are met:

        - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease
        - The member must currently be on around-the-clock opioid therapy of at least 60 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts
            - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12.5 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
    - Both of the following are met:
        - The member has established opioid tolerability by using short acting opioids daily for at least 90 days prior to request for long-acting opioid as evidenced by paid claims or pharmacy printouts
        - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
    - The member resides in a facility with skilled nursing care
    - The member must have taper plan of one or both agents
    - The opioid medication must be prescribed by, or in consult with, with an oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if the cumulative daily dose of opioids exceeds 90 MME/day

*Fentanyl Patch:*

- The member must have a BMI ≥17

*Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

*<u>Renewal Criteria - Approval Duration:</u> 12 months*

- One of the following must be met:
    - Documentation noting progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
    - The member must be stable on long-acting opioid medication for 2 years or longer

# Opioid Use Disorder

## Mono Product

### *Oral Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | buprenorphine tablets++ |

++ Clinically Non-Preferred: Naloxone is added to buprenorphine to prevent misuse. When taken correctly, a baby will have little to no absorption of naloxone which a growing body of evidence show is safe. Taking combination product during pregnancy or breastfeeding means that products don't need to be switched to a different medication after the baby is born during this high anxiety time. Risk of withdrawal to a neonate is a labeled warning on each product. Pregnancy and breastfeeding are not listed as contraindications on either product.

**References**:


1. *Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.*
2. *Perry, Briana N. MD; Vais, Simone BA; Miller, Melissa BA; Saia, Kelley A. MD. Buprenorphine-Naloxone Versus Buprenorphine for Treatment of Opioid Use Disorder in Pregnancy [07E]. Obstetrics & Gynecology 135():p 51S, May 2020. | DOI: 10.1097/01.AOG.0000663444.50960.74*
3. *Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.*


### *Prior Authorization Criteria*

Prior Authorization Form – Opioid Dependence

*Initial Criteria - Approval Duration: 1 year*

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
  - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
  - Allergy to oral naloxone is extremely rare and must be well documented.
  - Any request for transmucosal buprenorphine should include justification why long-acting injectable buprenorphine can't be used (while need for long-term transmucosal stability will not be considered, limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product - maximum of 14 days for Sublocade, and 1 dose for Brixadi)

### *Non-Oral Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BRIXADI (buprenorphine) | |
| SUBLOCADE (buprenorphine) | |

## Combination Product

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| buprenorphine-naloxone tablets | BUNAVAIL FILM (buprenorphine/naloxone) |
| | buprenorphine/naloxone film |
| | SUBOXONE FILM (buprenorphine/naloxone) |
| | ZUBSOLV (buprenorphine/naloxone) |

### *Prior Authorization Criteria*

- See DAW (Dispense As Written) Criteria

# Clostridioides difficile-associated diarrhea (CDAD)

## Prevention

**Fecal Microbiota**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| REBYOTA (fecal microbiota, live–jslm) SUSPENSION – *Medical Billing Only* | |
| VOWST (fecal microbiota spores, live-brpk) CAPSULE | |

**Monoclonal Antibody**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ZINPLAVA (bezlotaoxumab) – *Medical Billing Only* | |

### *Electronic Duration Verification:*

- Rebyota and Vowst is payable every 6 months.

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- The member has one of the following (1 or 2):
  3. The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year
  4. The member has had at least one previous episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year AND one of the following
     - *C. difficile* infection was severe (defined as ZAR score ≥ 2)
     - Member is immunocompromised

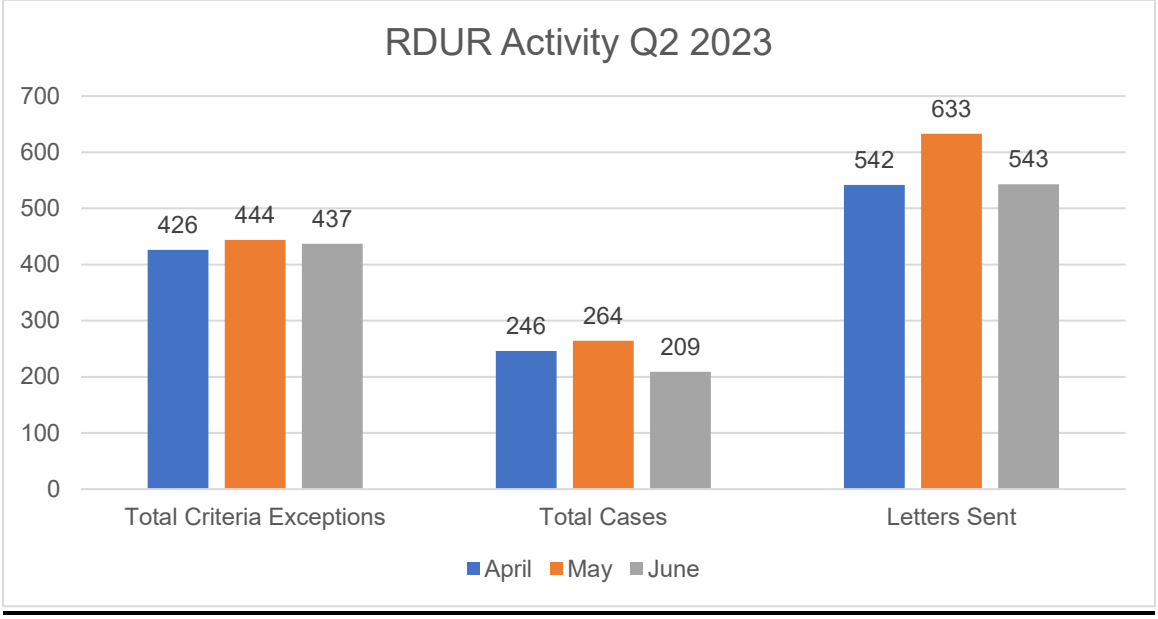
# Medications that cost over $3000/month

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request

# RDUR Activity Overview: Q2 2023




| April Cases by Type of Criteria | | |
|---|---|---|
| **Criteria Description** | **# of Cases** | **% of Cases** |
| **Clinical Appropriateness** | 45 | 18.3% |
| **Drug-Disease Interactions** | 148 | 60.2% |
| **Drug-Drug Conflicts** | 53 | 21.5% |

| May Cases by Type of Criteria | | |
|---|---|---|
| **Criteria Description** | **# of Cases** | **% of Cases** |
| **Adverse Effects** | 13 | 4.9% |
| **Drug-Disease Interactions** | 251 | 95.1% |

| June Cases by Type of Criteria | | |
|---|---|---|
| **Criteria Description** | **# of Cases** | **% of Cases** |
| **Drug-Disease Interactions** | 38 | 18.2% |
| **Drug-Drug Conflicts** | 169 | 80.9% |
| **Therapeutic Duplication** | 2 | 1.0% |

## Hyperparathyroidism

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcitrol | doxercalciferol |
| paricalcitrol | HECTOROL (doxercalciferol) |
| | RAYALDEE ER (calcifediol) |
| | ROCALTROL (calcitriol) |
| | SENSIPAR (cinacalcet) |
| | ZEMPLAR (paricalcitrol) |

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

*Cinacalet Only:*

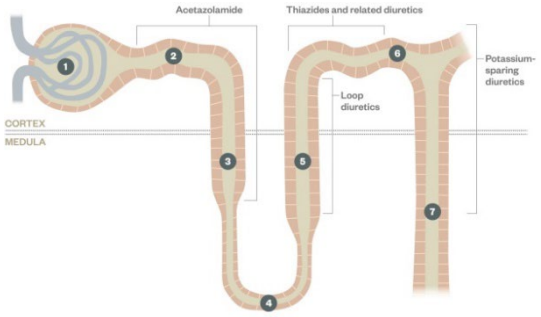
- If member is on renal dialysis, Medicare eligibility must be ruled out.

**References:**

1. *Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA, 2023*

# REVIEW OF DIURETICS

Diuretics are oftentimes used in heart failure (HF) and hypertension (HTN) due to their ability to increase excretion of sodium and water. Diuretics consist of different classes based on their mechanism of action including loop, thiazide, potassium sparing, and carbonic anhydrase inhibitors. Carbonic anhydrase inhibitors are not included in the chart below due to their limited use as diuretics.




Per the Pharmaceutical Journal, Diuretic Therapy Explained

| | Loop | Thiazides | Potassium (K)-Sparing | |
|---|---|---|---|---|
| Drugs | Bumetanide<br>Ethacrynic acid<br>Furosemide<br>Torsemide | Chlorthalidone<br>Hydrochlorothiazide<br>Indapamide<br>Metolazone | Amiloride<br>Triamterene | Spironolactone<br>Eplerenone |
| Mechanism | Inhibits sodium-chloride (Na-Cl) reabsorption in the ascending loop of Henle | Inhibits Na reabsorption in the distal tubule | Inhibits Na reabsorption in exchange for K at the distal tubule | Aldosterone antagonist |
| Primary use | **HF**: fluid retention | **HTN** | Added to limit **hypokalemia** caused by other diuretics | • Resistant **HTN**<br>• **HF**: ascites |
| Key notes | • Sulfonamide derivatives (except ethacrynic acid)<br>• Electrolyte imbalances (including hypokalemia) | | • Risk of hyperkalemia, requires monitoring of K levels in patients at higher risk | |

## Triamterene

**FDA Approval**

Triamterene: 505(j) Abbreviated New Drug Application (ANDA) pathway, standard

| Cost of Potassium-Sparing Diuretics Per Year | |
|---|---|
| Amiloride: $109.50<br>• Plus HCTZ ($10.95): $120.45<br>• Amiloride/HCTZ combination: $251 | Spironolactone: $36.50<br>Plus HCTZ ($10.95): $47.45<br>• Spironolactone/HCTZ combination: $427.05 |
| Triamterene: $4,872.75<br>• Plus HCTZ ($7.30): $4,880.05<br>• Triamterene/HCTZ combination: $73 | Eplerenone: $474.50<br>• No combination products |

*Based on adult dosing at lowest per unit WAC cost.*

| Advantages | Disadvantages |
|---|---|
| • Limits hypokalemia when used alongside other diuretics | • Mono product increases pill burden and may decrease adherence<br>• Cost is higher for mono product, and the most frequent use is in combination with HCTZ<br>• Not a first line agent for HTN per guideline recommendations<br>• Risk of hyperkalemia |

**References:**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2. *Brater DC, Ellison DH. Loop diuretics: Dosing and major side effects. UpToDate, January 24, 2023. https://www.uptodate.com/contents/loop-diuretics-dosing-and-major-side-effects?search=diuretic&topicRef=2338&source=see_link*
3. *Loop Diuretics. Drug Facts And Comparisons, March 9, 2020. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5545873?cesid=3hUS8YbzYwE&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dloop%2Bdiuretics%26t%3Dname%26acs%3Dtrue%26acq%3Dloop%26nq%3Dtrue*
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# REVIEW OF MENOPAUSE

Menopause is caused by decreased ovarian production of estrogen and other hormones with age. Patients may experience vasomotor symptoms (VMS) and genitourinary syndrome (GSM) which can decrease quality-of-life (QOL).

| **VMS:** hot flashes | **GSM:** vulvovaginal atrophy (dryness, dyspareunia) |
|---|---|
| First line: systemic hormonal therapy<br>* **Non-hormonal treatment** is recommended for women who are unable to take first line agents due to contraindications, comorbidities, or patient preference | First line: local therapies<br>• Low-dose vaginal estrogens<br>• Ospemifene<br>• Lubricants |

| **Hormonal Therapy**<br>• Most effective for VMS and GSM<br>• Shown to prevent bone loss and fractures | | | |
|---|---|---|---|
| Drug class | **Estrogen** | **Estrogen-progestin** | **Estrogen-SERM: Duavee** |
| Patient population | Women who have had a hysterectomy | Women who have an intact uterus | Women who cannot tolerate progestin |
| Formulations | Multiple formulations for systemic and local use | | Oral |
| Warnings | Risk of cardiovascular disease (CVD), hormonal cancer, lipid effects | | |
| Cost per year | Ranges from approximately $21.92± to $3,660.95‡ | | $2,325.05 |
| Contraindications | • History of hormone dependent cancer<br>• History of venous thromboembolism (VTE), myocardial infarction (MI) or transient ischemic attack (TIA)<br>• Liver disease<br>• Unexplained vaginal bleeding, thrombophilia disorders<br>• Pregnancy | | |
| **Non-Hormonal Therapy**<br>• Indicated for VMS<br>• Recommended for patients who cannot take or are hesitant to take hormonal therapies | | | |
| Medication | **Paroxetine** | **Veozah** | |
| Mechanism | SSRI | Neurokinin-3 (NK3) receptor antagonist | |
| Key Points | Beneficial for patients also suffering from depression | • Liver function tests are needed every 3 months within the first year due to the risk of hepatic impairment<br>• Contraindicated in liver and kidney impairment | |
| Cost per year | $1,671.70 | $6,690.45 | |

*Based on adult dosing at lowest per unit WAC cost. ± Oral estradiol ‡ Activella*
**** Medications that do not have an FDA approved indication for menopause but are used off-label: selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), gabapentin, clonidine, oxybutynin.*

## Veozah

**FDA Approval**

Veozah: 505(b) New Drug Application (NDA) pathway, Type 1 – New Molecular Entity, PRIORITY

| **Advantages** | **Disadvantages** |
|---|---|
| • Alternative for patients who are unable or hesitant to take hormonal therapy<br>• No risk of VTE or cancer | • Cost<br>• Liver dysfunction<br>• Frequent liver function tests required<br>• Minimal data and long-term effects are unknown<br>• No head-to-head trials<br>• Doesn't treat GSM symptoms |

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# NORTH DAKOTA MEDICAID
# RETROSPECTIVE DRUG UTILIZATION REVIEW
# CRITERIA RECOMMENDATIONS
# 3RD QUARTER 2023

***Criteria Recommendations*** ***Approved*** ***Rejected***

**1. Elacestrant / Overuse** _____ _____

Alert Message: Orserdu (elacestrant) may be over-utilized. The recommended dosage of elacestrant is 345 mg taken orally with food once daily until disease progression or unacceptable toxicity occurs.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | | |

Max Dose: 345 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**2. Elacestrant / Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Orserdu (elacestrant) in pediatric patients have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**3. Elacestrant / Severe Hepatic Impairment** _____ _____

Alert Message: Avoid the use of Orserdu (elacestrant) in patients with severe hepatic impairment (Child-Pugh C). Elacestrant has not been studied in patients with severe hepatic impairment.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Cirrhosis | |
| | Liver Failure | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**4. Elacestrant 345 mg / Moderate Hepatic Impairment** _____ _____

Alert Message: Patients who have moderate hepatic impairment (Child-Pugh B) taking Orserdu (elacestrant) should receive a reduced dose. The recommended dose of elacestrant in patients with moderate hepatic impairment is 258 mg once daily. In pharmacokinetic studies, the AUC of elacestrant increased in subjects with moderate hepatic impairment (Child-Pugh B) by 83%. There were no clinically significant differences in the Cmax and AUC of elacestrant in subjects with mild hepatic impairment (Child-Pugh A).

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Moderate Hepatic Impairment | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**5. Elacestrant / Dyslipidemia** _____ _____

Alert Message: In clinical trials, hypercholesterolemia and hypertriglyceridemia occurred in patients taking Orserdu (elacestrant) at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking elacestrant.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Hypercholesterolemia | |
| | Hypertriglyceridemia | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**6. Elacestrant / Strong and Moderate CYP3A4 Inducers** _____ _____

Alert Message: The concurrent use of Orserdu (elacestrant) with a moderate or strong CYP3A4 inducer should be avoided. Elacestrant is a CYP3A4 substrate, and concomitant use with a strong or moderate CYP3A4 inducer may decrease elacestrant exposure, which may decrease the effectiveness of elacestrant.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Apalutamide | |
| | Bosentan | |
| | Carbamazepine | |
| | Efavirenz | |
| | Etravirine | |
| | Phenobarbital | |
| | Phenytoin | |
| | Primidone | |
| | Rifabutin | |
| | Rifampin | |
| | Rifapentine | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**7. Elacestrant / Strong and Moderate CYP3A4 Inhibitors** _____ _____

Alert Message: The concurrent use of Orserdu (elacestrant) with a moderate or strong CYP3A4 inhibitor should be avoided. Elacestrant is a CYP3A4 substrate, and concomitant use with a strong or moderate CYP3A4 inhibitor may increase elacestrant exposure, which may increase the risk of elacestrant-related adverse reactions.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Elacestrant | Atazanavir | Fosamprenavir | |
| | Aprepitant | Idelalisib | |
| | Cimetidine | Itraconazole | |
| | Ciprofloxacin | Ketoconazole | |
| | Clarithromycin | Nefazodone | |
| | Clotrimazole | Nelfinavir | |
| | Cobicistat | Posaconazole | |
| | Crizotinib | Ritonavir | |
| | Cyclosporine | Tipranavir | |
| | Diltiazem | Verapamil | |
| | Dronedarone | Voriconazole | |
| | Erythromycin | | |
| | Fluconazole | | |
| | Fluvoxamine | | |

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**8. Elacestrant / BCRP Substrates** _____ _____

Alert Message: Orserdu (elacestrant) is a BCRP inhibitor. In drug interaction studies, the concomitant use of elacestrant with a BCRP substrate increased the plasma concentrations of a BCRP substrate. Concurrent use of elacestrant with a BCRP substrate may increase the risk for adverse reactions associated with a BCRP substrate. Reduce the dosage of BCRP substrates per the BCRP substrate prescribing information when minimal concentration changes may lead to serious or life-threatening adverse reactions.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Elacestrant | Alpelisib | Prazosin | |
| | Atorvastatin | Rosuvastatin | |
| | Dantrolene | Sulfasalazine | |
| | Dolutegravir | Talazoparib | |
| | Methotrexate | Tenofovir | |
| | Pazopanib | Topotecan | |
| | Pibrentasvir | | |

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**9. Elacestrant / P-gp Substrates** _____ _____

Alert Message: Orserdu (elacestrant) is a P-gp inhibitor. In drug interaction studies, concomitant use of elacestrant with a P-gp substrate increased the concentrations of P-gp substrate. Concurrent use of elacestrant with a P-gp substrate may increase the risk for adverse reactions associated with a P-gp substrate. Reduce the dosage of P-gp substrates per the P-gp substrate prescribing information when minimal concentration changes may lead to serious or life-threatening adverse reactions.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Cyclosporine | |
| | Digoxin | |
| | Sirolimus | |
| | Tacrolimus | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**10. Elacestrant / Pregnancy / Pregnancy Negating** _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Orserdu (elacestrant) can cause fetal harm when administered to a pregnant woman. Administration of elacestrant to pregnant rats resulted in adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at maternal exposures below the recommended dose based on the area under the curve (AUC). Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with elacestrant and for 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Elacestrant | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**11. Elacestrant / Lactation** _____ _____

Alert Message: There are no data on the presence of Orserdu (elacestrant) in human milk, its effects on milk production, or the breastfed child. Because of the potential for serious adverse reactions in the breastfed child, advise lactating women to not breastfeed during treatment with elacestrant and for 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**12. Elacestrant / Therapeutic Appropriateness** _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Orserdu (elacestrant) and for 1 week after the last dose. Based on findings in animals and its mechanism of action, elacestrant can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Elacestrant | | Contraceptives |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**13. Elacestrant / Therapeutic Appropriateness** _____ _____

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Orserdu (elacestrant) and for 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | | |

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

**14. Elacestrant / Non-adherence** _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Orserdu (elacestrant). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Elacestrant | | |

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**15. Betamethasone Spray / Therapeutic Appropriateness - Pediatric** _____ _____

Alert Message: The safety and effectiveness of Sernivo (betamethasone spray) in patients younger than 18 years of age have not been studied. Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface-to-body mass ratios. The use of betamethasone spray is not recommended in pediatric patients.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Betamethasone Spray | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

**16. Betamethasone Spray / Therapeutic Appropriateness - Duration** _____ _____

Alert Message: The use of Sernivo (betamethasone spray) is recommended for up to 4 weeks of treatment. Treatment with betamethasone spray beyond 4 weeks is not recommended.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Betamethasone Spray | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

**17. Betamethasone Spray / Glaucoma, Cataracts & IOP** _____ _____

Alert Message: The use of topical corticosteroids, including Sernivo (betamethasone spray), may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts, glaucoma, and intraocular pressure have been reported postmarketing with the use of topical corticosteroid products, including betamethasone dipropionate. Advise patients to avoid contact with betamethasone spray with the eyes and to report any visual symptoms.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Betamethasone Spray | Cataracts<br>Glaucoma | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

**18. Betamethasone Spray / Therapeutic Appropriateness** _____ _____

Alert Message: Sernivo (betamethasone spray) can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during or after the withdrawal of treatment. Factors that predispose to HPA axis suppression include the use of high-potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Betamethasone Spray | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

***Criteria Recommendations*** ***Approved*** ***Rejected***

**19. Betamethasone Spray / Lactation** _____ _____

Alert Message: There are no data regarding the presence of betamethasone dipropionate in human milk, the effects on the breastfed infant, or the effects on milk production after topical application of Sernivo (betamethasone spray) to women who are breastfeeding. It is possible that topical administration of betamethasone dipropionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for betamethasone spray and any potential adverse effects on the breastfed infant from betamethasone spray or the underlying maternal condition.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Betamethasone Spray | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

**20. Atorvastatin Suspension / Overuse** _____ _____

Alert Message: Atorvaliq (atorvastatin suspension) may be over-utilized. The maximum recommended dose of atorvastatin suspension in adults is 80 mg per day.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Atorvastatin Suspension | | |

Max Dose: 80 mg/day
Age Range: 18 – 999 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

**21. Atorvastatin Suspension / Overuse** _____ _____

Alert Message: Atorvaliq (atorvastatin suspension) may be over-utilized. The maximum recommended dose of atorvastatin suspension in pediatric patients 10 years of age and older with homozygous familial hypercholesterolemia (HoFH) is 80 mg per day. The maximum recommended dose of atorvastatin suspension in pediatric patients 10 years of age and older with heterozygous familial hypercholesterolemia (HeFH) is 20 mg per day.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Atorvastatin Suspension | | |

Max Dose: 80 mg/day
Age Range: 10 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**22. Atorvastatin Suspension / Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Atorvaliq (atorvastatin suspension) have not been established in pediatric patients younger than 10 years of age with HeFH or HoFH, or in pediatric patients with other types of hyperlipidemia (other than HeFH or HoFH).

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Atorvastatin Suspension | | |

Age Range: 0 - 9 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

**23. Rosuvastatin / Darolutamide** _____ _____

Alert Message: In patients taking Nubeqa (darolutamide), the dose of rosuvastatin should not exceed 5 mg once daily. Rosuvastatin is a BCRP substrate, and concurrent use with darolutamide, a BCRP inhibitor, has been shown to elevate rosuvastatin concentrations, increasing the risk of statin-associated adverse reactions.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Rosuvastatin | Darolutamide | |

Max Dose: 5 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

**24. Rosuvastatin / Regorafenib** _____ _____

Alert Message: In patients taking regorafenib, the dose of rosuvastatin should not exceed 10 mg once daily. Rosuvastatin is a BCRP substrate, and concurrent use with regorafenib, a BCRP inhibitor, has been shown to elevate rosuvastatin concentrations increasing the risk of statin-associated adverse reactions.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Rosuvastatin | Regorafenib | |

Max dose: 10 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**25. Atogepant / Severe Hepatic Impairment** _____ _____

Alert Message: Due to the potential for liver injury in patients with severe hepatic impairment, avoid the use of Qulipta (atogepant) in this patient population. In pharmacokinetic studies, atogepant exposure was increased by 38% in patients with severe (Child-Pugh Class C) hepatic impairment compared to patients with normal hepatic function.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Atogepant | Cirrhosis | |
| | Hepatic Failure | |

References:
Qulipta Prescribing Information, April 2023, AbbVie.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**26. Tucatinib / Overuse** _____ _____

Alert Message: Tukysa (tucatinib) may be over-utilized. The recommended daily dosage of tucatinib is 300 mg orally twice daily.

Drugs/Disease

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Tucatinib | | Cirrhosis |
| | | Hepatic Failure |

Max Dose: 600 mg/day

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**27. Tucatinib / Overuse – Hepatic Impairment** _____ _____

Alert Message: Tukysa (tucatinib) may be over-utilized. For patients with severe hepatic impairment (Child-Pugh C), the recommended dosage of tucatinib is 200 mg orally twice daily.

Drugs/Disease

| Util A | Util B | Util C (Include) |
|---|---|---|
| Tucatinib | | Cirrhosis |
| | | Hepatic Failure |

Max Dose: 400 mg/day

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**28. Tucatinib / Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Tukysa (tucatinib) in pediatric patients have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**29. Tucatinib / Strong CYP3A4 Inducers or Moderate 2C8 Inducers** _____ _____ Alert Message:
Concomitant use of Tukysa (tucatinib) with a strong CYP3A or moderate CYP2C8 inducer decreased tucatinib plasma concentrations, which may reduce tucatinib activity. Avoid the concomitant use of tucatinib with a strong CYP3A inducer or a moderate CYP2C8 inducer. If concomitant use with a strong CYP2C8 inhibitor cannot be avoided, reduce the recommended dosage to 100 mg orally twice daily.

Drugs/Disease

| Util A | Util B | | Util C |
|---|---|---|---|
| Tucatinib | Apalutamide | Phenobarbital | |
| | Carbamazepine | Phenytoin | |
| | Enzalutamide | Primidone | |
| | Mitotane | Rifampin | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**30. Tucatinib / Strong CYP2C8 Inhibitors** _____ _____
Alert Message: The concurrent use of Tukysa (tucatinib) with strong CYP2C8 inhibitors should be avoided. If concomitant use with a strong CYP2C8 inhibitor cannot be avoided, reduce the recommended dosage to 100 mg orally twice daily. After discontinuation of the strong CYP2C8 inhibitor for 3 elimination half-lives, resume the tucatinib dose that was taken prior to initiating the inhibitor.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | Gemfibrozil | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**31. Tucatinib / CYP3A Substrates w/ NTI** _____ _____
Alert Message: In drug interaction studies, concomitant use of Tukysa (tucatinib) with a CYP3A substrate increased the plasma concentrations of the CYP3A substrate, which may increase the toxicity associated with a CYP3A substrate. Avoid concomitant use of tucatinib with CYP3A substrates, where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP3A substrate dosage in accordance with approved product labeling.

Drugs/Disease

| Util A | Util B | | | | | Util C |
|---|---|---|---|---|---|---|
| Tucatinib | Avanafil | Eletriptan | Lurasidone | Simvastatin | Vardenafil | |
| | Budesonide | Eplerenone | Maraviroc | Sirolimus | | |
| | Buspirone | Everolimus | Midazolam | Tacrolimus | | |
| | Conivaptan | Felodipine | Naloxegol | Ticagrelor | | |
| | Darifenacin | Ibrutinib | Nisoldipine | Tipranavir | | |
| | Darunavir | Lomitapide | Quetiapine | Tolvaptan | | |
| | Dronedarone | Lovastatin | Sildenafil | Triazolam | | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* | |
|---|---|---|---|

**32. Tucatinib / P-gp w/ NTI** _____ _____ Alert Message:

In drug interaction studies, concomitant use of Tukysa (tucatinib) with a P-gp substrate increased the plasma concentrations of the P-gp substrate, which may increase the toxicity associated with a P-gp substrate. Consider reducing the dosage of P-gp substrates, where minimal concentration changes may lead to serious or life-threatening toxicities.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | Cyclosporine | Sirolimus |
| | Digoxin | Tacrolimus |
| | Everolimus | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**33. Tucatinib / Diarrhea** _____ _____ Alert Message:

Tukysa (tucatinib) can cause severe diarrhea. If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue tucatinib.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | Diarrhea | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**34. Tucatinib / Hepatotoxicity** _____ _____

Alert Message: Tukysa (tucatinib) can cause severe hepatotoxicity. Monitor ALT, AST, and bilirubin prior to starting tucatinib, every 3 weeks during treatment, and as clinically indicated. Based on the severity of hepatotoxicity, interrupt dose, then dose reduce or permanently discontinue tucatinib.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | | |

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**35. Tucatinib / Pregnancy / Pregnancy Negating** _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Tukysa (tucatinib) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of tucatinib to pregnant rats and rabbits during organogenesis caused embryo-fetal mortality, reduced fetal weight and fetal abnormalities at maternal exposures >/= 3 times the human exposure (AUC) at the recommended dose. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with tucatinib and for at least 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Tucatinib | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**36. Tucatinib / Lactation** _____ _____

Alert Message: There are no data on the presence of Tukysa (tucatinib) or its metabolites in human or animal milk or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with tucatinib. and for 1 week after the last dose. Tucatinib is used in combination with trastuzumab and capecitabine. Refer to the full prescribing information of trastuzumab and capecitabine for lactation information.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**37. Tucatinib / Therapeutic Appropriateness** _____ _____ Alert Message:

Advise females of reproductive potential to use effective contraception during treatment with Tukysa (tucatinib) and for at least 1 week after the last dose. Based on findings from animal studies and its mechanism of action, Tukysa (tucatinib) can cause fetal harm when administered to a pregnant woman.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | | |

Gender: Female
Age Range: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**38. Tucatinib / Therapeutic Appropriateness** _____ _____ Alert Message:
Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Tukysa (tucatinib) and for 1 week after the last dose.

Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | | |

Gender: Male

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

**39. Tucatinib / Non-adherence** _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Tukysa (tucatinib). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tucatinib | | |

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence with Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

**40. Mavacamten / Black Box Warning** _____ _____
Alert Message: Camzyos (mavacamten) reduces systolic contraction and can cause heart failure or totally block ventricular function. Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction and heart failure. New or worsening arrhythmia, dyspnea, chest pain, fatigue, palpitations, leg edema, or elevations in N-terminal pro B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should also prompt an evaluation of cardiac function.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | Heart Failure | |
| | Arrhythmias | |
| | Dyspnea | |
| | Angina | |
| | Palpitations | |
| | Localized Edema | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**41. Mavacamten / Contraindication (Black Box)** _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a moderate to strong CYP2C19 inhibitor or a strong CYP3A4 inhibitor is contraindicated. Concomitant use with a moderate to strong CYP2C19 or a strong CYP3A4 inhibitor increases mavacamten exposure, which may increase the risk of heart failure due to systolic dysfunction.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Mavacamten | Cobicistat | Ketoconazole | |
| | Clarithromycin | Nefazodone | |
| | Esomeprazole | Nelfinavir | |
| | Felbamate | Posaconazole | |
| | Fluconazole | Ritonavir | |
| | Fluvoxamine | Ticlopidine | |
| | Fluoxetine | Voriconazole | |
| | Itraconazole | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

**42. Mavacamten / Contraindication (Black Box)** _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a moderate to strong CYP2C19 inducer or a moderate to strong CYP3A4 inducer is contraindicated. Concomitant use with a moderate to strong CYP2C19 inducer or a moderate to strong CYP3A4 inducer decreases mavacamten exposure, which may reduce the efficacy of mavacamten. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers as the levels of induced enzyme normalize.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Mavacamten | Apalutamide | Phenytoin | |
| | Bosentan | Rifabutin | |
| | Butalbital | Rifampin | |
| | Carbamazepine | Rifapentine | |
| | Efavirenz | | |
| | Enzalutamide | | |
| | Etravirine | | |
| | Mitotane | | |
| | Phenobarbital | | |
| | Primidone | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**43. Mavacamten / Weak CYP2C19 Inhibitors & Moderate 3A4 Inhibitors** _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor increases mavacamten exposure, which may increase the risk of adverse drug reactions. Initiate mavacamten at the recommended starting dosage of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dose of mavacamten by one level (i.e., 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on mavacamten treatment and intend to initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable treatment with 2.5 mg of mavacamten because a lower dose is not available.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Mavacamten | Aprepitant | Erythromycin | |
| | Ciprofloxacin | Esomeprazole | |
| | Cimetidine | Imatinib | |
| | Conivaptan | Omeprazole | |
| | Crizotinib | Verapamil | |
| | Cyclosporine | | |
| | Diltiazem | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

**44. Mavacamten / Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Camzyos (mavacamten) have not been established in pediatric patients.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

**45. Mavacamten / Disopyramide** _____ _____

Alert Message: Avoid concomitant use of Camzyos (mavacamten) in patients on disopyramide or disopyramide in combination with verapamil or diltiazem. Concurrent use of mavacamten and disopyramide will have additive negative inotropic effects. Concomitant use of mavacamten with disopyramide in combination with verapamil or diltiazem has been associated with left ventricular systolic dysfunction and heart failure symptoms in patients with obstructive HCM.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | Disopyramide | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**46. Mavacamten / Ranolazine** _____ _____

Alert Message: Coadministration of ranolazine with Camzyos (mavacamten) is contraindicated due to decreased ranolazine exposure and efficacy. Ranolazine is a CYP3A substrate, and mavacamten is a moderate CYP3A inducer. Patients on therapy with ranolazine were excluded from the clinical trial of mavacamten in obstructive HCM (EXPLORER-HCM).

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | Ranolazine | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Ranexa Prescribing Information, Oct. 2019, Gilead Sciences, Inc.

**47. Mavacamten / Combined Hormonal Contraceptives** _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with hormonal contraceptives that are CYP3A4 substrates may lead to contraceptive failure or an increase in breakthrough bleeding. Mavacamten is a CYP3A4 inducer and can induce the metabolism of progestin and ethinyl estradiol. Advise patients to use a contraceptive method that is not affected by CYP450 enzyme induction (e.g., intrauterine system) or add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of mavacamten.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | Contraceptives | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

**48. Mavacamten / Pregnancy / Pregnancy Negating** _____ _____

Alert Message: Camzyos (mavacamten) may cause fetal toxicity when administered to a pregnant female, based on findings in animal studies. Confirm the absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with mavacamten and for 4 months after the last dose. Mavacamten may reduce the effectiveness of combined hormonal contraceptives (CHCs). Advise patients using CHCs to use an alternative contraceptive method that is not affected by CYP450 enzyme induction or to add nonhormonal contraception.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Mavacamten | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

***Criteria Recommendations*** ***Approved*** ***Rejected***

**49. Mavacamten / Lactation** _____ _____

Alert Message: The presence of Camzyos (mavacamten) in human or animal milk, the drug's effects on the breastfed infant, and the effects on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for mavacamten and any potential adverse effects on the breastfed child from mavacamten or from the underlying maternal condition.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Mavacamten | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

**50. Baclofen Granules / Overuse** _____ _____

Alert Message: Lyvispah (baclofen granules) may be over-utilized. The maximum recommended dosage of baclofen granules is 80 mg daily (20 mg four times a day).

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Baclofen granules | | |

Max Dose: 80 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

**51. Baclofen Granules / Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Lyvispah (baclofen granules) in pediatric patients below the age of 12 have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Baclofen granules | | |

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**52. Baclofen Granules / Renal Impairment** _____ _____

Alert Message: Because baclofen is primarily excreted unchanged through the kidneys, Lyvispah (baclofen granules) should be given with caution to patients with renal impairment, and it may be necessary to reduce the dosage.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Baclofen granules | Renal Impairment | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

**53. Baclofen Granules / Pregnancy / Pregnancy Negating** _____ _____

Alert Message: There are no adequate data on the risk of major birth defects, miscarriages, or other maternal adverse outcomes associated with the use of Lyvispah (baclofen granules) in pregnant women. There are adverse effects on fetal outcomes associated with withdrawal from baclofen after delivery. Oral administration of baclofen to pregnant rats resulted in an increased incidence of fetal structural abnormalities at a dose which was also associated with maternal toxicity.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Baclofen granules | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

**54. Baclofen Granules / Lactation** _____ _____

Alert Message: At recommended oral doses, Lyvispah (baclofen) is present in human milk. Withdrawal symptoms can occur in breastfed infants when maternal administration of baclofen is stopped, or when breastfeeding is stopped. There are no adequate data on other effects of baclofen on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for baclofen and any potential adverse effects on the breastfed infant from baclofen or from the underlying maternal condition.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Baclofen granules | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

| *Criteria Recommendations* | *Approved* | *Rejected* |
|---|---|---|

**55. Perampanel /Therapeutic Appropriateness** _____ _____

Alert Message: The safety and effectiveness of Fycompa (perampanel) in pediatric patients less than 4 years of age have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Perampanel | | |

Age Range: 0 – 3 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.