GEORGIA DEPARTMENT OF COMMUNITY HEALTH

# Georgia Department of Community Health

# DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health

## April 16, 2025

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GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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**DRUG UTILIZATION REVIEW BOARD MEETING**
**AGENDA**
*2 Martin Luther King Jr. Drive, S.E.*
*Atlanta, Georgia 30334*
*Department of Community Health Board Room - Room 470-A*
*East Tower, Balcony Level*
**Wednesday, April 16, 2025**
**10:00 a.m. to 2:00 p.m.**

| | |
|---|---|
| **CALL TO ORDER** | *Gurinder J.S. Doad, M.D., Ph.D., Chair* |
| **MINUTES FROM PREVIOUS MEETING** | *Chair* |
| **EXTERNAL COMMENTS SESSION** | *Chair* |
| **CLINICAL REVIEWS** | *Chadwick Nicholson, PharmD, NorthStar*<br>*Mary-Beth Plum, PharmD, BCACP, NorthStar*<br>*Emily Baker, PharmD, BCPS, NorthStar* |

- **New Drugs**
  - Cobenfy
  - Ebglyss
  - Kisunla
  - Nemluvio
  - Ohtuvayre

| | |
|---|---|
| **ADJOURNMENT OF OPEN SESSION** | *Chair* |
| **EXECUTIVE SESSION** | *Afzal Mistry, PharmD, Prime Therapeutics*<br>*Nina Bandali, PharmD, Prime Therapeutics* |
| **RECONVENING OF OPEN SESSION** | *Chair* |
| **BOARD'S RECOMMENDATIONS AND VOTES** | *Chair* |
| **FUTURE AGENDA ITEMS** | *Chair* |
| **ADJOURNMENT OF MEETING** | *Chair* |

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# Department of Community Health
# Drug Utilization Review Board (DURB)
# MINUTES
# Wednesday, January 22, 2025

**MEMBERS PRESENT**
Osgood (Drew) A. Miller, R.Ph. , Vice-Chair
Alton Condra, III, R.Ph.
M. Celeste Fowler, Pharm.D., HCMBA
Glenda Wrenn Gordon, M.D., MSHP, FAPA
Burton L. Lesnick, M.D., FAAP
Robyn Lorys, Pharm.D.
J. Russell (Rusty) May, Pharm.D.
Matthew Perri, Pharm.D., R.Ph., Ph.D.
Suzanne Walton, Pharm.D., BCPS, BCOP

**MEMBERS ABSENT**
Doug Collins, M.D.
Gurinder Doad, M.D., Ph.D., Chair
Torey Jones, Pharm.D.
Brent L. Rollins, R.Ph., Ph.D.
Danny A. Toth, R.Ph.

**Staff**
Peter D'Alba, Pharm.D., Pharmacy Director, Pharmacy Services
Gilletta Gray, R.Ph., Clinical Manager, Pharmacy Services
Ashlee Henry, MSHI, Pharmacy Operations Supervisor
Ashley Bellino, Pharmacy Operations Specialist, Pharmacy Services
Rose Duncan, MBA, Operations Analyst-Drug Rebate Program, Pharmacy Services
Lori Garner, MHS, MBA, R.Ph., Pharmacist, SHBP
Karla Forbes, Pharm.D., Program Integrity

**NorthStar HealthCare Consulting**
Emily Baker, Pharm.D., BCPS, MHA, MBA, President
Chad Nicholson, Pharm.D., Clinical Programs Director
Mary-Beth Plum, Pharm.D., BCACP, Clinical Pharmacist

**OptumRx**
Mark Hall, MBA, PMP, Assoc. Director, Government and Public Sector Markets
Kelly Coleman, CPhT, Account Manager, Government and Public Sector Markets
Talmahjia "Tami" Sweat, Pharm.D., Clinical Consulting

**Magellan Rx Management/Prime Therapeutics**
Afzal "Fez" Mistry, Pharm.D., Pharmacist Account Manager
Nina Bandali, Pharm.D., Senior Director, PDL Management

**Care Management Organizations**
Turkesia Robertson-Jones, Pharm.D., CareSource
Cassandra Tancil, Pharm.D., BCPS, Amerigroup

**Department of Community Health**
**Drug Utilization Review Board (DURB)**
**MINUTES**
**Wednesday, January 22, 2025**

## Call to Order

The Drug Utilization Review Board (DURB/DUR Board/Board) held its first meeting for the calendar year on January 22, 2025. The Vice-Chair, Osgood (Drew) A. Miller, R.Ph., called the meeting to order at 10:03am.

## Minutes from the Previous Meeting

Vice-Chair Miller asked for corrections or changes to the minutes from the October 16, 2024 meeting. A motion was made (Burton L. Lesnick, M.D., FAAP) and seconded (J. Russell (Rusty) May, Pharm.D.) and carried to approve the minutes as written.

## External Comments Session

There were no external comments presented to the Board. Due to state building closures and the change to a virtual meeting for the DUR Board meeting, public comments will be accepted via written submission. Written comments and Disclosure Forms should be e-mailed to GAMedicaid@nhc-llc.com. The Disclosure Form can be found on the DCH DUR Board website under Consumer Comment Opportunities. Public comments submitted in writing will be sent securely to the DUR Board members.

## New Drug Reviews

Clinical information for the following new drugs, in the market six months or more, was presented for discussion and recommendations. The complete detailed drug summary is in the New Drugs for Review section of the DUR Board binder.

| Therapeutic Class | Drugs | Presenter |
|---|---|---|
| | | |
| **Hemophilia Agents** | ***Beqvez*** | Chad Nicholson, Pharm.D. |
| | | |
| **Duchenne Muscular Dystrophy Agents** | ***Duvyzat*** | Chad Nicholson, Pharm.D. |
| | | |
| **Leukodystrophy Agents** | ***Lenmeldy*** | Mary-Beth Plum, Pharm.D., BCACP |
| | | |
| **Pulmonary Arterial Hypertension Agents** | ***Winrevair*** | Mary-Beth Plum, Pharm.D., BCACP |
| | | |

The Board discussed the drug information, provided comments, and raised questions on the following:

- Beqvez – Beqvez uses slightly different vector than Hemgenix but they are in the same viral family so presumably if there are neutralizing antibodies to one, it may impact another; cross reactivity does not seem to be a given; someone who responded to a previous gene therapy could be a candidate for this gene therapy, although highly unlikely someone would use two different gene therapies, but can't rule it out; question on previous gene therapy in criteria due

to cost and not knowing how patients would respond after receiving gene therapy previously; requests and appeals can be handled on a case by case basis; Utilization Management Criteria uses evidence based practice, and for patients outside of that, there is an appeal process; appeals are reviewed by clinical pharmacist or physician; physicians can request a peer to peer review prior to any adverse determination.

- Duvyzat – oral product and placed on Preferred Drug List (outpatient pharmacy); advantage over IV infusion products; ongoing therapy – challenge to evaluate outcomes; once on it, would be allowed to stay on; given the side effect profile, may want to evaluate safety components on renewal; can be reevaluated at 6 months or annually once established on therapy; some side effects did equate to some discontinuations.
- Lenmeldy – longest term follow-up – 6-7 years; consider modifying criteria for diagnosis confirmation from all of criteria to two of the three criteria, because a novel mutation may not be identified.
- Winrevair – Pregnancy - shared decision making; advise of risks and to use contraception; animal studies showed birth defects associated with the drug; can use sterile precautions when handling the drug (can check NIOSH list); ongoing studies and data – PA criteria will be updated; monthly reviews of FDA approved indications or changes in labeling and information seen during the review of appeals; some pediatric patients may straddle some of the WHO categories and may see some requests for use in this population.

**DCH Decisions**

DCH Decisions from the October 2024 DUR Board meeting were provided in the DCH Decision section of the DUR Board binder.

**Upcoming Meetings**

The following upcoming meetings were announced:

- Drug Utilization Review Board
  2 Martin Luther King Jr. Drive, SE
  East Tower
  Atlanta, Georgia 30334

| | |
|---|---|
| Wednesday, April 16, 2025: | 10:00am –2:00pm |
| Wednesday, July 16, 2025: | 10:00am –2:00pm |
| Wednesday, October 15, 2025: | 10:00am –2:00pm |

**Disclosure Forms**

Disclosure forms were received and reviewed by the Department for completeness for all Board members attending the meeting.

**Adjournment of Open Session**

The DUR Board voted to have the Executive Session pursuant to the Open Meetings Act of Georgia Section 50-14-1 – 50-14-6 and pursuant to Federal Law Section 1396R-8B3D. The individuals recorded in attendance with the Board members were from the Department of Community Health, Prime Therapeutics, NorthStar HealthCare Consulting, and OptumRx. A motion was made by M. Celeste Fowler, Pharm.D., HCMBA and seconded by Alton Condra, III, R.Ph., to approve the closed session. There was a unanimous vote approving the closed session. The Vice-Chair, Osgood (Drew) A. Miller,

R.Ph., adjourned the open session at approximately 11:48am, at which time members took a break then reconvened for the executive (closed) session.

**Executive Session**
The Executive Session was held from 11:57am to 12:15pm.

**Reconvening of Open Session**
The DUR Board reconvened for the open session at 12:23pm.

**Board's Recommendations to the Department**
After all clinical and financial evaluations and discussions, the DUR Board voted and presented the Department with the following recommendations for changes to the Preferred Drug List (PDL) or Physician Administered Drug List (PADL) as noted in Attachment A. All motions and votes are noted in Attachment B.

**Future Agenda Items**
The were no future agenda items noted.

**Conclusion**
At the conclusion of the open session and no other business for discussion, Vice-Chair Miller adjourned the meeting at 12:28pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2025.

_____
Osgood (Drew) A. Miller, R.Ph., Vice-Chair

**Drug Utilization Review Board**
**Motions - Votes - New Drugs**
**January 22, 2025**

| New Drug | | PDL Status | Motion - Recommendations | Additional Comments | |
|---|---|---|---|---|---|
| **Hemophilia Agents** | **Beqvez** | **N/A** | **Pending contract negotiations** | | |
| **Board Members - Present** (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
| 1 ~~Collins, Douglas, M.D.~~ | | | | | |
| 2 Condra III, Alton, R.Ph. | | | √ | | |
| 3 ~~Doad, Gurinder J.S., M.D., Ph.D.-**Chair**~~ | | | | | |
| 4 Fowler, M. Celeste, Pharm.D., HCMBA | | | √ | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | √ | | |
| 6 ~~Jones, Torey, Pharm.D.~~ | | | | | |
| 7 Lesnick, Burton, M.D., FAAP | | √ | √ | | |
| 8 Lorys, Robyn, Pharm.D. | | | √ | | |
| 9 May, J. Russell (Rusty), Pharm.D. | √ | | √ | | |
| 10 Miller,Osgood (Drew) A., R.Ph.-**Vice-Chair** | | | √ | | |
| 11 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | √ | | |
| 12 ~~Rollins, Brent L., R.Ph., Ph.D.~~ | | | | | |
| 13 ~~Toth, Danny, R.Ph.~~ | | | | | |
| 14 Walton, Suzanne, Pharm.D., BCPS, BCOP | | | √ | | |
| | | TOTAL | 9 | 0 | 0 |

| New Drug | | PDL Status | Motion - Recommendations | Additional Comments | |
|---|---|---|---|---|---|
| **Duchenne Muscular Dystrophy Agents** | **Duvyzat** | N/A | **NP/PA** | | |
| **Board Members - Present** (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
| 1 ~~Collins, Douglas, M.D.~~ | | | | | |
| 2 Condra III, Alton, R.Ph. | | √ | √ | | |
| 3 ~~Doad, Gurinder J.S., M.D., Ph.D.-**Chair**~~ | | | | | |
| 4 Fowler, M. Celeste, Pharm.D., HCMBA | √ | | √ | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | √ | | |
| 6 ~~Jones, Torey, Pharm.D.~~ | | | | | |
| 7 Lesnick, Burton, M.D., FAAP | | | √ | | |
| 8 Lorys, Robyn, Pharm.D. | | | √ | | |
| 9 May, J. Russell (Rusty), Pharm.D. | | | √ | | |
| 10 Miller,Osgood (Drew) A., R.Ph.-**Vice-Chair** | | | √ | | |
| 11 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | √ | | |
| 12 ~~Rollins, Brent L., R.Ph., Ph.D.~~ | | | | | |
| 13 ~~Toth, Danny, R.Ph.~~ | | | | | |
| 14 Walton, Suzanne, Pharm.D., BCPS, BCOP | | | √ | | |
| | | TOTAL | 9 | 0 | 0 |

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments |
|---|---|---|---|---|

**Drug Utilization Review Board**
**Motions - Votes - New Drugs**
**January 22, 2025**

| | Leukodystrophy Agents | Lenmeldy | N/A | P/PA-PADL | | |
|---|---|---|---|---|---|---|
| | **Board Members - Present** (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
| 1 | ~~Collins, Douglas, M.D.~~ | | | | | |
| 2 | Condra III, Alton, R.Ph. | | | √ | | |
| 3 | ~~Doad, Gurinder J.S., M.D., Ph.D.-**Chair**~~ | | | | | |
| 4 | Fowler, M. Celeste, Pharm.D., HCMBA | | | √ | | |
| 5 | Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | √ | | |
| 6 | ~~Jones, Torey, Pharm.D.~~ | | | | | |
| 7 | Lesnick, Burton, M.D., FAAP | √ | | √ | | |
| 8 | Lorys, Robyn, Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty), Pharm.D. | | | √ | | |
| 10 | Miller,Osgood (Drew) A., R.Ph.-**Vice-Chair** | | | √ | | |
| 11 | Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | √ | | |
| 12 | ~~Rollins, Brent L., R.Ph., Ph.D.~~ | | | | | |
| 13 | ~~Toth, Danny, R.Ph.~~ | | | | | |
| 14 | Walton, Suzanne, Pharm.D., BCPS, BCOP | | √ | √ | | |
| | | | TOTAL | 9 | 0 | 0 |

| | New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments | |
|---|---|---|---|---|---|---|
| | Pulmonary Arterial Hypertension Agents | Winrevair | N/A | NP/PA | | |
| | **Board Members - Present** (Strike out, when absent) | Motion Maker (√) | Seconded By (√) | VOTES YES (√) | NO (√) | ABSTAIN (√) |
| 1 | ~~Collins, Douglas, M.D.~~ | | | | | |
| 2 | Condra III, Alton, R.Ph. | | | √ | | |
| 3 | ~~Doad, Gurinder J.S., M.D., Ph.D.-**Chair**~~ | | | | | |
| 4 | Fowler, M. Celeste, Pharm.D., HCMBA | | | √ | | |
| 5 | Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | √ | √ | | |
| 6 | ~~Jones, Torey, Pharm.D.~~ | | | | | |
| 7 | Lesnick, Burton, M.D., FAAP | | | √ | | |
| 8 | Lorys, Robyn, Pharm.D. | | | √ | | |
| 9 | May, J. Russell (Rusty), Pharm.D. | | | √ | | |
| 10 | Miller,Osgood (Drew) A., R.Ph.-**Vice-Chair** | | | √ | | |
| 11 | Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | √ | | |
| 12 | ~~Rollins, Brent L., R.Ph., Ph.D.~~ | | | | | |
| 13 | ~~Toth, Danny, R.Ph.~~ | | | | | |
| 14 | Walton, Suzanne, Pharm.D., BCPS, BCOP | √ | | √ | | |
| | | | TOTAL | 9 | 0 | 0 |

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Prime THERAPEUTICS™

# Listed below are Preferred Drug List changes for the State of Georgia Fee-For-Service Medicaid and PeachCare for Kids Programs

**Effective April 1, 2025 (see chart below)***

DCH rebate vendor, Prime Therapeutics, has reviewed specific drugs at the January 2025 DURB meeting and corresponding supplemental rebate offers. The Preferred Drug List (PDL)/Providers' Administered Drug List (PADL) decisions/changes for categories reviewed are outlined below. For a full listing of our PDL, go to www.dch.georgia.gov/pharmacy and select the "Preferred Drug Lists" option; for the PADL, go to https://www.mmis.georgia.gov/portal/ and select "Provider Information", "Fee Schedule", then "Providers' Administered Drug List."

| PREFERRED AGENTS | NON-PREFERRED AGENTS |
|---|---|
| **DUCHENNE AGENTS** | |
| | DUVYZAT (ORAL) SUSPENSION – PA |
| **LEUKODYSTROPHY AGENTS** | |
| LENMELDY (INTRAVENOUS) SUSPENSION* – PA | |
| **PULMONARY ARTERIAL HYPERTENSION AGENTS** | |
| | WINREVAIR (SUBCUTANEOUS) POWDER FOR INJECTION – PA |

*PADL drugs may be subject to a different effective date.

GEORGIA DEPARTMENT OF COMMUNITY HEALTH

# Georgia Department of Community Health (GDCH) Opportunities for Pharmaceutical Manufacturer Input on Clinical Recommendations and Clinical Management Strategies by the Drug Utilization Review Board

Clinical Information and Clinical Management Strategies relevant to the GDCH Medicaid Fee-For-Service program will be presented to the Drug Utilization Review Board (DURB) at each meeting through OptumRx by its vendor NorthStar HealthCare Consulting (NHC). Manufacturer input on new and existing drugs is welcomed and appreciated using these opportunities. **Please note that new drug entities are generally not reviewed by the DURB until the drug has been on the market for at least 6 months.**

## Ongoing Opportunity:

**DUR Board Meeting Process:** New drugs, therapeutic classes and/or supplemental rebate classes under review will be posted to the DCH website at **http://dch.georgia.gov/durb-meeting-information** approximately 30 days prior to the Manufacturers' Forum. Input specific to the drugs under review from manufacturers are made directly to NHC via **GAMedicaid@nhc-llc.com** and reported as appropriate by NHC at subsequent DURB meetings.

Upon review of information, and based on its expertise and discussions, the DURB makes recommendations to GDCH.

## Presentation Opportunity:

**Manufacturers' Forum:** A forum prior to each relevant DURB meeting whereby manufacturers may present:

1) Clinical information relevant to a new drug on the market under review by the DURB at the next meeting.
2) Clinical information relevant to ongoing NHC/OptumRx clinical management strategies (e.g. review of drug benefit plan designs, new drugs coming to market, new indications, etc.) as deemed necessary by NHC/OptumRx.

Please see the Manufacturers' Forum Announcement at **http://dch.georgia.gov/durb-meeting-information**.

## Opportunity to Appeal to GDCH:

**GDCH Review Process:** DURB recommendations are reviewed by GDCH for final decisions. Manufacturers may request an appeal meeting directly with GDCH after conclusion of each quarterly DURB meeting and **this appeal meeting must be conducted within 10 business days following the DURB meeting**. **Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov**

**Questions not addressed in this document may be sent to NorthStar HealthCare Consulting by e-mail: GAMedicaid@nhc-llc.com**

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# 2025

# Upcoming Meetings

## Drug Utilization Review Board Meeting

2 Martin Luther King Jr. Drive, S.E.
Atlanta, Georgia 30334
Department of Community Health Board Room - Room 470-A
East Tower, Balcony Level

| | |
|---|---|
| Wednesday, July 16, 2025: | 10:00am – 2:00pm |
| Wednesday, October 15, 2025: | 10:00am – 2:00pm |