

Georgia Department of Community Health

DRUG UTILIZATION REVIEW BOARD MEETING

Department of Community Health

January 17, 2024







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, January 17, 2024 10:00 a.m. to 2:00 p.m.

CALL TO ORDER

Celeste Fowler, PharmD, MBA, Chair

MINUTES FROM PREVIOUS MEETING

EXTERNAL COMMENTS SESSION

CLINICAL REVIEWS

- > New Drugs
 - •Elevidys
 - ●Inpefa
 - Roctavian
 - ●Veozah
 - Zavzpret

ADJOURNMENT OF OPEN SESSION

EXECUTIVE SESSION

RECONVENING OF OPEN SESSION

BOARD'S RECOMMENDATIONS AND VOTES

FUTURE AGENDA ITEMS

ADJOURNMENT OF MEETING

Chair Chair

Afzal Mistry, PharmD, NorthStar Chad Nicholson, PharmD, NorthStar Emily Baker, PharmD, BCPS, NorthStar

Chair Nina Bandali, PharmD, Pharmacist Account Manager, Magellan Rx Management Chair Chair Chair

Chair





Department of Community Health Drug Utilization Review Board (DURB) MINUTES Tuesday, September 26, 2023

Department of Community Health Drug Utilization Review Board (DURB) MINUTES Tuesday, September 26, 2023

MEMBERS PRESENT

M. Celeste Fowler, Pharm.D., HCMBA, Chair Gurinder Doad, M.D., Ph.D., Vice-Chair Doug Collins, M.D. Alton Condra, III, R.Ph. Torey Jones, Pharm.D. Burton L. Lesnick, M.D., FAAP Robyn Lorys, Pharm.D. J. Russell (Rusty) May, Pharm.D. Osgood (Drew) A. Miller, R.Ph. Danny A. Toth, R.Ph. Suzanne Walton, Pharm.D., BCPS, BCOP

MEMBERS ABSENT

Glenda Wrenn Gordon, M.D., MSHP, FAPA Otto Goyco, M.D. Matthew Perri, Pharm.D., R.Ph., Ph.D. Brent L. Rollins, R.Ph., Ph.D.

<u>Staff</u>

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

NorthStar HealthCare Consulting

Emily Baker, Pharm.D., BCPS, MHA, MBA, President Afzal "Fez" Mistry, Pharm.D., Clinical Programs Director Chad Nicholson, Pharm.D., Clinical Pharmacist Catherine "Amy" Baker, Pharm.D., Clinical Pharmacist

<u>OptumRx</u>

Mark Hall, MBA, PMP, Assoc. Director, Government and Public Sector Markets Talmahjia "Tami" Sweat, Pharm.D., Clinical Consulting

Magellan Rx Management

Nina Bandali, Pharm.D., Pharmacist Account Manager

Care Management Organizations

Turkesia Robertson-Jones, Pharm.D., CareSource

Department of Community Health Drug Utilization Review Board (DURB) MINUTES Tuesday, September 26, 2023

<u>Call to Order</u>

The Drug Utilization Review Board (DURB/DUR Board/Board) held its third meeting for the calendar year virtually on September 26, 2023 via Zoom. The Chair, M. Celeste Fowler, Pharm.D., HCMBA, called the meeting to order at 10:10am after Board members introduced themselves.

Minutes from the Previous Meeting

Chair Fowler asked for corrections or changes to the minutes from the June 13, 2023 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

The following external comment was presented to the Board:

• Chair Celeste Fowler read a letter submitted by Nancy Pitra (Director of Government Affairs) from the Alzheimer's Association to allow equitable access to Leqembi.

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.

| | D | D (|
|---------------------------|----------|------------------------------|
| Therapeutic Class | Drugs | Presenter |
| | | |
| Multiple Sclerosis Agents | Briumvi | Afzal "Fez" Mistry, Pharm.D. |
| | | |
| Alzheimer's Agents | Leqembi | Afzal "Fez" Mistry, Pharm.D. |
| | | |
| HIV/AIDS | Sunlenca | Chad Nicholson, Pharm.D. |
| | | |
| Disease Modifier, T1DM | Tzield | Chad Nicholson, Pharm.D. |

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

- Briumvi
 - Comparability to Ocrevus and other products some indirect comparisons but hard to determine which is more potent since no head-to-head studies; rely on expert consensus and refer to agents that have already been on the market
 - Agents for Relapsing Remitting not really looking at symptoms but choice depends on patient and physician determining what would lead to best adherence for patient

Tuesday, September 26, 2023

- Leqembi
 - Study trials excluded patients if any bleeding risks
 - At least three MRIs required to monitor for amyloid related imaging abnormalities (ARIA); Pet Scan and MRI required prior to treatment
 - Stratification to determine mild vs. advanced disease mainly look at patient or caregiver reported systems, scans.
 - Phase IV trials open label extended study ongoing
 - HEAD Study looking at early disease (amyloid elevation without Alzheimer symptoms)
 - Will check with manufacturer if looking at targeting certain biomarkers
 - Difficult to stratify which patients to give these drugs to; a lot of unknown
 - Modest cognitive decline but translates to 4-5 months delay in disease progression
 - Trickier situation if patient doesn't have cognitive symptoms
 - Concerns about use of drug in men vs. women; mostly used in women who aren't affected as much by cognitive decline
 - Minority population underrepresented in trials
- Sunlenca
 - Give consideration to frequency of dosing (when comparing with Trozargo); offers convenience and flexibility; advantage for compliance
- Tzield
 - Stage 2 screening testing for autoantibodies not routine; now pushing to have more routine screening
 - Off label to reduce insulin requirements; not approvable criteria but can monitor; no data on impact of another dose
 - Exciting development; may be difficult to find patients
 - Rise in diagnosis seen after influenza and COVID infections, so this time frame may offer window of opportunity to identify patients
 - Didn't see study treatment protocols for prophylaxis of secondary infections (e.g. CMV)
 - 14 day regimen daily outpatient infusions, transportation could be problematic

DCH Decisions

DCH Decisions from the June 2023 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
Martin Luther King Jr. Drive, SE
East Tower
Atlanta, Georgia 30334
(*Conducted via Zoom Webinars until further notice*)

Department of Community Health Drug Utilization Review Board (DURB) MINUTES Tuesday, September 26, 2023

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, Magellan Rx Management, NorthStar HealthCare Consulting, and OptumRx. A motion was made by Burton L. Lesnick, M.D., FAAP and seconded (Danny A. Toth, R.Ph.) to approve the closed session. There was a unanimous vote approving the closed session. The Chair, M. Celeste Fowler, Pharm.D., HCMBA, 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 11:53am to 12:18pm.

Reconvening of Open Session

The DUR Board reconvened for the open session at 12:28pm.

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

There were no future agenda items noted.

Conclusion

At the conclusion of the open session and no other business for discussion, Chair Fowler adjourned the meeting at 12:36pm.

THESE MINUTES ARE HEREBY APPROVED AND ADOPTED, THIS THE _____ DAY OF _____, 2023.

Drug Utilization Review Board Motions - Votes - New Drugs <mark>September 26, 2023</mark>

| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments | Comments |
|---|---------------------------------|------------|-----------------------------|---------------------|-------------|
| Multiple Sclerosis Agents | Briumvi (Intravenous) Injection | N/A | P/PA on PADL | | |
| Board Members - Present | Motion | Seconded | | VOTES | |
| (Strike out, when absent) | Maker (V) | By (V) | YES (V) | (v) ON | ABSTAIN (V) |
| 1 Collins, Douglas, M.D. | | | | | |
| 2 Condra III, Alton, R.Ph. | | | V | | |
| 3 Doad, Gurinder J.S., M.D., Ph.DVice-Chair | | | V | | |
| 4 Fowler, M. Celeste, Pharm D., HCMBA-Chair | | | | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | | | |
| 6 Goyco, Otto, M.D. | | | | | |
| 7 Jones, Torey, Pharm D. | | | | | |
| 8 Lesnick, Burton, M.D., FAAP | ~ | | 1 | | |
| 9 Lorys, Robyn, Pharm D | | | 1 | | |
| 10 May, J. Russell (Rusty), Pharm.D. | | Y | 1 | | |
| 11 Miller,Osgood (Drew) A., R.Ph. | | | ~ | | |
| 12 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | | | |
| 13 Rollins, Brent L., R.Ph., Ph.D. | | | | | |
| 14 Toth, Danny, R.Ph. | | | 1 | | |
| 15 Walton, Suzanne, Pharm D., BCPS, BCOP | | | V | | |
| | | TOTAL | 8 | 0 | 0 |
| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments | Comments |
| Alzheimer's Agents | | | | | |
| | Leqembi (Intravenous) Injection | N/A | NP/PA on PADL | | |
| Board Members - Present | Motion Mater (A) | Seconded | VEC 140 | VOTES | |
| (Strike out, when absent) | | | | | |
| 1 Collins, Douglas, M.D. | | | | | |
| 2 Condra III, Alton, R.Ph. 3 Doad, Gurinder J.S., M.D., Ph.DVice-Chair | | | | | |
| Fowler M Celeste Pharm D HCMBA-Chair | | | | | |
| S Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | | | |
| B Govern Otto M D | | | | | |
| 7 Jones, Torey, Pharm.D. | | | | | |
| 8 Lesnick, Burton, M.D., FAAP | | | 1 | | |
| 9 Lorys, Robyn, Pharm D. | > | | 7 | | |
| 10 May, J. Russell (Rusty), Pharm D. | | | 7 | | |
| 11 Miller, Osgood (Drew) A., R.Ph. | | 1 | 1 | | |
| 12 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | | | |
| 13 Rollins, Brent L., R.Ph., Ph.D. | | | | | |
| 14 Toth, Danny, R.Ph. | | | \wedge | | |
| 15 Walton, Suzanne, Pharm D., BCPS, BCOP | | | 1 | | |
| | | TOTAL | 9 | 0 | 0 |
| | | | | | |

Drug Utilization Review Board Motions - Votes - New Drugs <mark>September 26, 2023</mark>

| New Drug | Drug | PDL Status | Recommendations | Additional Comments | Comments |
|---|--------------------------------------|--------------------|-----------------------------|---------------------|-------------|
| HIV/AIDS | Sunlenca (Oral) Tablet | N/A | NP/PA on PDL | | |
| | Sunlenca (Subcutaneous) Injection | ∀/N | NP/PA on PADL | | |
| Board Members - Present | Motion Maker (v) | Seconded Bv (v) | YES (V) | VOTES NO (V) | ABSTAIN (V) |
| 1 Collins, Douglas, M.D. | | | | | |
| 2 Condra III, Alton, R.Ph. | 7 | | | | |
| 3 Doad, Gurinder J.S., M.D., Ph.DVice-Chair | | | 1 | | |
| 4 Fowler, M. Celeste, Pharm D., HCMBA-Chair | | | | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | | | |
| 6 Goyco, Otto, M.D. | | | | | |
| 7 Jones, Torey, Pharm.D. | | | | | |
| 8 Lesnick, Burton, M.D., FAAP | | | ^ | | |
| 9 Lorys, Robyn, Pharm D. | | | \wedge | | |
| 10 May, J. Russell (Rusty), Pharm D. | | | \checkmark | | |
| 11 Miller, Osgood (Drew) A., R. Ph. | | | \wedge | | |
| 12 Perri, Matthew, R.Ph., Pharm D., Ph.D. | | | | | |
| 13 Rollins, Brent L., R.Ph., Ph.D. | | | | | |
| 14 Toth, Danny, R.Ph. | | | 1 | | |
| 15 Walton, Suzanne, Pharm D., BCPS, BCOP | | 7 | 7 | | |
| | | TOTAL | 7 | 0 | 0 |
| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments | Comments |
| HIV/AIDS | Trogarzo (Intravenous) Injection | JDA on PADL | NP/PA on PADL | | |
| Board Members - Present | Motion | | | VOTES | |
| (Strike out, when absent) | Maker (V) | By (V) | YES (V) | (v) ON | ABSTAIN (V) |
| 1Collins, Douglas, M.D. | | | | | |
| 2 Condra III, Alton, R.Ph. | ~ | | | | |
| | | | 1 | | |
| 4 Fowler, M. Celeste, Pharm D., HCMBA-Chair | | | | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | | | |
| 6 Goyco, Otto, M.D. | | | | | |
| 7 Jones, Torey, Pharm.D. | | | | | |
| 8 Lesnick, Burton, M.D., FAAP | | | 1 | | |
| 9 Lorys, Robyn, Pharm.D. | | | V | | |
| 10 May, J. Russell (Rusty), Pharm D. | | | V | | |
| | | | ۲ | | |
| 12 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | | | |
| 13 Rollins, Brent L., R.Ph., Ph.D. | | | | | |
| 14 Toth, Danny, R.Ph. | | | 1 | | |
| 15 Walton, Suzanne, Pharm D., BCPS, BCOP | | ٧ | V | | |
| | | TOTAL | 7 | 0 | 0 |
| | | | | | |

| | September 26, 2023 | 123 | | | |
|---|--------------------------------|------------|-----------------------------|---------------------|-------------|
| New Drug | Drug | PDL Status | Motion - Recommendations | Additional Comments | comments |
| Disease Modifier, T1DM | Tzield (Intravenous) Injection | N/A | NP/PA on PADL | | |
| Board Members - Present | Motion | Seconded | | VOTES | |
| (Strike out, when absent) | Maker (v) | By (V) | YES (V) | (v) ON | ABSTAIN (V) |
| 1 Collins, Douglas, M.D. | | | | | |
| 2 Condra III, Alton, R.Ph. | | | | | |
| 3 Doad, Gurinder J.S., M.D., Ph.DVice-Chair | ~ | | ~ | | |
| 4 Fowler, M. Celeste, Pharm D., HCMBA-Chair | | | | | |
| 5 Gordon, Glenda Wrenn, M.D., MSHP, FAPA | | | | | |
| 6 Goyco, Otto, M.D. | | | | | |
| 7 Jones, Torey, Pharm D. | | | | | |
| 8 Lesnick, Burton, M.D., FAAP | | | \wedge | | |
| 9 Lorys, Robyn, Pharm D. | | | \wedge | | |
| 10 May, J. Russell (Rusty), Pharm D. | | | \wedge | | |
| 11 Miller, Osgood (Drew) A., R.Ph. | | | \wedge | | |
| 12 Perri, Matthew, R.Ph., Pharm.D., Ph.D. | | | | | |
| 13 Rollins, Brent L., R.Ph., Ph.D. | | | | | |
| 14 Toth, Danny, R.Ph. | | 1 | ~ | | |
| 15 Walton, Suzanne, Pharm D., BCPS, BCOP | | | \wedge | | |
| | | TOTAL | 2 | 0 | 0 |
| | | | | | |

Drug Utilization Review Board Motions - Votes - New Drugs September 26, 2023





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

Effective January 1, 2024 (see chart below)*

DCH rebate vendor, Magellan Medicaid Administration (MMA), has reviewed specific drugs at the September 2023 DURB meeting and corresponding supplemental rebate offers. The Preferred Drug List (PDL)/Provider's Administered Drug List (PADL) decisions/changes for categories reviewed are outlined below. For a full listing of our PDL, go to <u>www.dch.georgia.gov/pharmacy</u> and select the "Preferred Drug Lists" option; for the PADL, go to <u>https://www.mmis.georgia.gov/portal/</u> and select "Provider Information", "Fee Schedule", then "Provider's Administered Drug List."

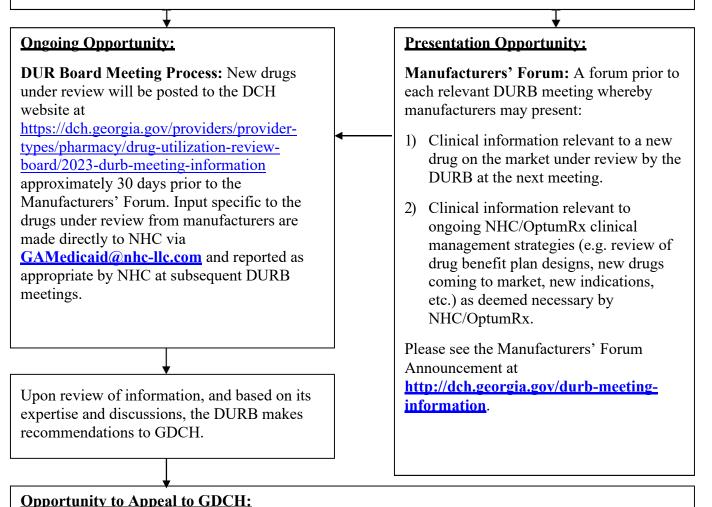
| PREFERRED AGENTS | NON-PREFERRED AGENTS | |
|-----------------------------|--------------------------|--|
| ALZHEIME | R'S AGENTS | |
| | LEQEMBI (INTRAVEN)* - PA | |
| DISEASE MODIFIER, T1DM | | |
| TZIELD (INTRAVEN)* - PA | | |
| HIV / AIDS | | |
| SUNLENCA TABLET (ORAL) - PA | | |
| SUNLENCA (SUBCUT)* - PA | | |
| TROGARZO (INTRAVEN)* - PA | | |
| MULTIPLE SCLEROSIS AGENTS | | |
| BRIUMVI (INTRAVEN.)*- PA | | |
| BRIUMVI (INTRAVEN.)*- PA | | |

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



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.**



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**. <u>Contact: Shirmary Hodges at (404) 656-4044 or shodges@dch.ga.gov</u>

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

2024Upcoming MeetingsDrug Utilization Review Board Meeting2 Martin Luther King Jr. Drive, S.E.Atlanta, Georgia 30334Department of Community Health Board Room - Room 470-AEast Tower, Balcony LevelWednesday, April 17, 2024:Martin 10:00am - 2:00pm

Wednesday, July 17, 2024:

10:00am - 2:00pm

Wednesday, October 16, 2024:

10:00am - 2:00pm

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| Board Member | Credentials | Specialty/Area of Expertise | Company Name |
|--------------------------------|----------------------|--|--|
| M. Celeste Fowler, Chair | Pharm.D., HCMBA | 340B Pharmacy | Piedmont Henry Hospital |
| Gurinder J.S. Doad, Vice-Chair | M.D., Ph.D. | Family Practice | Southwest Georgia Family Medicine and Mercer University School of Medicine |
| Douglas C. Collins | M.D. | Hematology/Oncology | Metro Hematology-Oncology, PC |
| Alton Condra III | R.Ph. | HIV/AIDS Pharmacy - Infectious Disease Program | Grady Memorial Hospital |
| Otto C. Goyco | M.D., FACP | Internal Medicine | Otto C. Goyco Internal Medicine, LLC |
| Torey A. Jones | Pharm.D., MBA | 340B Pharmacy | Phoebe Putney Health System, Bizzell Group, LLC, |
| Burton L. Lesnick | M.D., FAAP | Pediatrics/Pediatric Pulmonology | Children's Healthcare of Atlanta |
| Robyn Lorys | Pharm.D. | Academia - Professor | Mercer University College of Pharmacy |
| J. Russell May | Pharm.D. | Academia - Professor | University of Georgia College of Pharmacy |
| Drew A. Miller | R.Ph. | Retail Pharmacy | Wynn's Pharmacy |
| Matthew Perri III | Ph.D., R.Ph. | Academia - Professor | University of Georgia College of Pharmacy |
| Brent L. Rollins | R.Ph., Ph.D. | Academia - Professor | Philadelphia College of Osteopathic Medicine School of Pharmacy |
| Danny A. Toth | R.Ph. | Pharmacy Benefit Plans | Timber Ridge Consultants, LLC |
| Suzanne M. Walton | Pharm.D., BCPS, BCOF | Hematology/Oncology | Grady Health System |
| Glenda Wrenn | M.D. | Psychiatry, Academia - Professor | Morehouse School of Medicine |