RDLA

Rare Disease Legislative Advocates

POWERED BY THE EVERYLIFE FOUNDATION

Patient Involvement in Drug Utilization Boards

October 2023 Quarterly State Advocacy Webinar

What is Drug Utilization Review?

Drug Utilization Review is an authorized, structured, ongoing review of prescribing, dispensing, and use of medication.

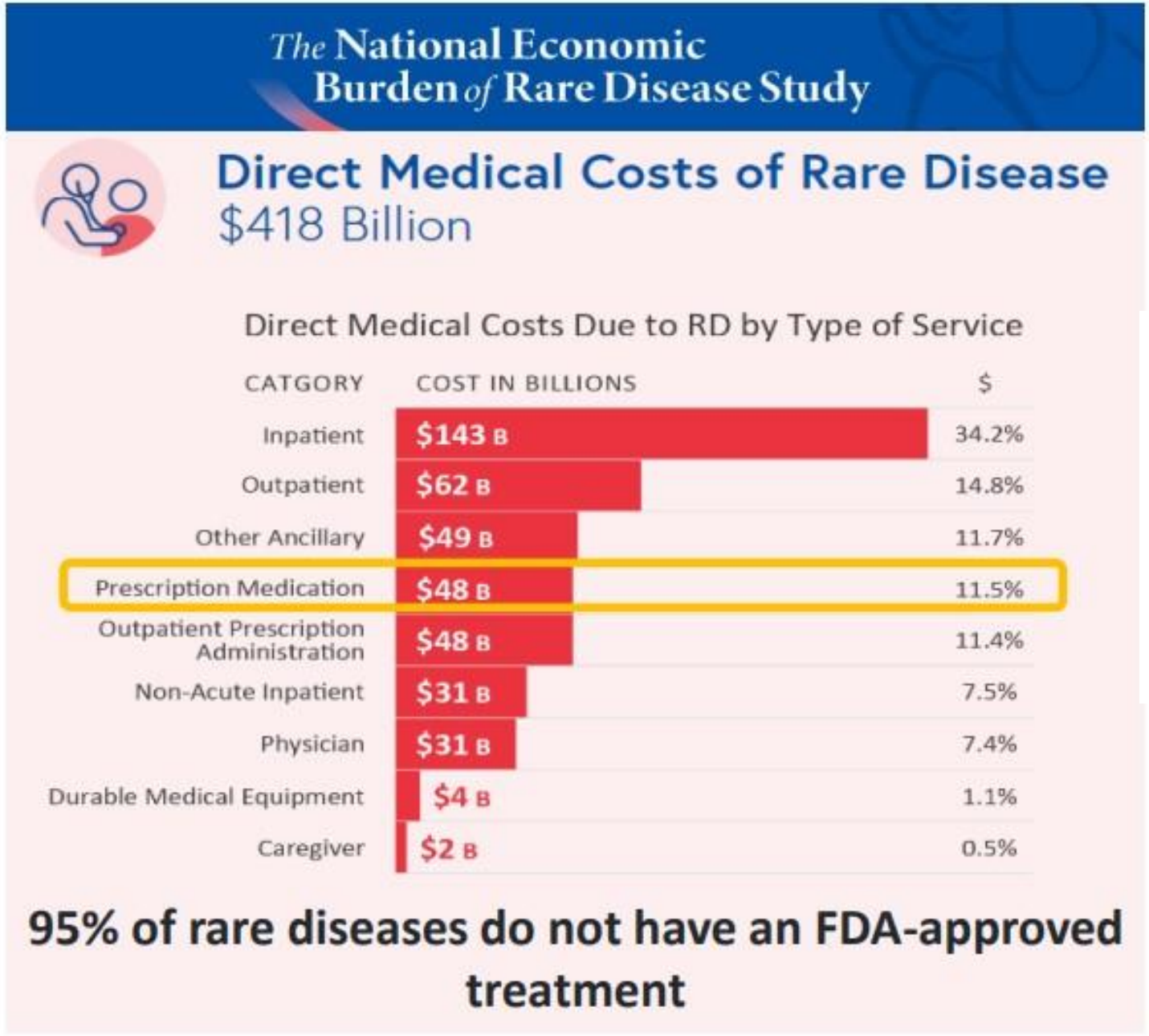
Under federal Medicaid rules, each state and Medicaid managed care organization must have a Drug Utilization Review program.

Functions of State DUR Boards

Determine how each drug will be covered by Medicaid

Create step therapy and prior authorization requirements

Educate physicians and pharmacists on issues identified through retrospective review activities (This can include recommendations for changes in prescribing and dispensing practices)



State DUR:

Patient Impact

DUR Boards can create criteria to restrict coverage that blocks patient access to drugs. Rare disease patients already face significant access barriers

With 10,000+ rare diseases, board and committee **members cannot have an in-depth understanding of the needs of each condition**.

Your Advocacy Matters!

As more rare disease patients engage with DUR Boards…

- Board members will **better understand the unique challenges faced by rare disease patients** and the specific treatments required to manage these conditions.

- Board members can **develop drug formularies that account for the needs of the rare disease community** and grant rare disease patients access to desperately needed care

State DUR Wish List

Transparency/Timeliness

- Public notice of meeting at least 30-days or consistent with State Open Meetings law, whichever is greater.
- Agenda including name of drugs being reviewed and speaking sign-up posted at least 14 days prior to scheduled meeting.
- Allow applications for speakers once agenda is posted.
- If coverage policy/criteria changes are proposed, those proposed changes are also posted.
- All methodologies for value assessments or other pricing determinations including those of the "underlying health economics considerations" should rely on multiple sources and become public within at least 30-days prior to the meeting or consistent with the State Open Meetings law.
- States require their Managed Care Organizations to publish their DUR/P&T meeting information and public coverage policies.

Patient/Advocate/Expert Participation

- Acceptance of written and oral testimony from patients and caregivers.
- Accessible meeting format for everyone.
- Virtual meeting attendance options continue to be available post-pandemic.
- Uniform processes across Medicaid agencies (i.e., meeting announcements, speaker policies).
- In states where there is an RDAC or a specialized utilization board, make use of that expertise in clinical reviews of rare disease or condition products.
  Alternatively, rare patient and specialist empaneled in committee.
- State programs perform outreach to advocacy organizations to identify rare disease expertise in each state.
- Committee consultation with specialist experienced in the treatment of applicable rare disease.
- Testimony is given prior to vote.

Policy/Access

- Prior authorization policy criteria/proposed criteria available publicly and easily accessible.
- Require all newly approved drugs for rare disease to be reviewed at the next medical coverage review meeting unless FDA approval becomes public less than 30 days prior to the meeting; require medical coverage review meetings to be conducted at least quarterly.
- Prohibit the sole use of QALYs to inform Medicaid coverage decisions or the use of such data points as part of coverage review discussions.
- Products approved under the Accelerated Approval Pathway are no longer considered experimental.
- Address coverage gaps upon FDA approval and any significant delays.

EveryLife Foundation DUR Research

Areas of Needed Improvement

- **Engaging rare disease expertise**
  - Outreach to advocacy organizations or RDAC
  - Rare patient and specialist empaneled in committee
  - Consultation with specialist experienced in rare treatment
- **Timely and appropriate review of rare disease drugs**
  - Require timely review of newly approved RD drugs
- **Public Transparency**
  - Easily findable/accessible websites and meeting information
  - MCOs publish utilization review meeting information as well
- **Legislator Education**
  - Might not understand what this is, why it matters to patients & how rare drugs differ from other drugs

ACCESS WORKING GROUP – TRANSPARENCY/TIMELINESS

- Public Notice of meeting at least 30-days or consistent with State Open Meetings law, whichever is greater.
- Agenda including name of drugs being reviewed and speaking sign-up posted at least 14 days prior to scheduled meeting.
- Allow applications for speakers once agenda is posted.
- If coverage policy/criteria changes are proposed, those proposed changes are also posted.
- All methodologies for value assessments or other pricing determinations including those of the "underlying health economics considerations" should rely on multiple sources and become public within at least 30-days prior to the meeting or consistent with the State Open Meetings law.
- States require their Managed care organizations to publish their DUR/P&T meeting information and public coverage policies.

AWG - PATIENT/ADVOCATE/EXPERT PARTICIPATION

- Acceptance of written and oral testimony from patients and caregivers.
- Virtual meeting attendance options continue to be available post COVID19.
- Uniform processes across Medicaid agencies (i.e., meeting announcements, speaker policies).
- In states where there is an RDAC or a specialized utilization board, make use of that expertise in clinical reviews of rare disease or condition products.

Alternatively, rare patient and specialist empaneled in committee.

- State programs perform outreach to advocacy organizations to identify rare disease expertise in each state.
- Testimony is given prior to vote.
- Accessible meeting format for everyone.
- Committee consultation with specialist experienced in the treatment of applicable rare disease.

AWG - POLICY/ACCESS

- Prior authorization policy criteria/proposed criteria available publicly and easily accessible.
- Require all newly approved drugs for rare disease to be reviewed at the next medical coverage review meeting unless FDA approval becomes public less than 30 days prior to the meeting; require medical coverage review meetings to be conducted at least quarterly.
- Prohibit the sole use of QALYs to inform Medicaid coverage decisions or the use of such data points as part of coverage review discussions.
- Products approved under the Accelerated Approval Pathway are no longer considered experimental.
- Address coverage gaps upon FDA approval and any significant delays.