

# State Legislative Efforts to Increase Patient Care

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# Conflict of Interests

- None to report

# Learning Objectives

- Review the Colorado Prescription Drug Affordability Review Board and Advisory Council (PDAB/PDACC) upper payment limit selection process
- Identify and review state legislative bills that impact oncology patient access and care

Colorado Prescription Drug Affordability  
Review Board and Advisory Council  
(PDAB/PDAAC)





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# PDAB History

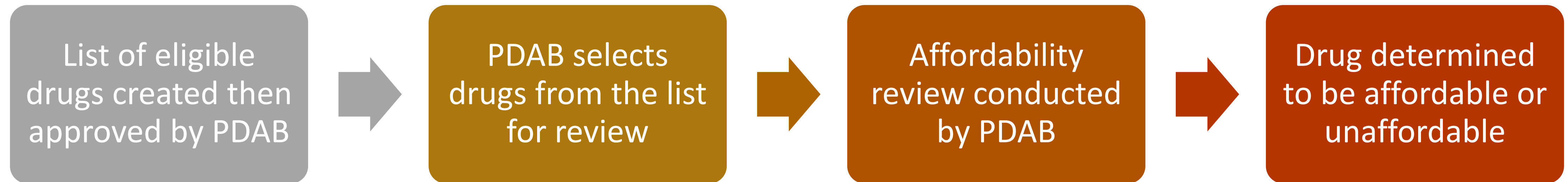
- Established by Senate Bill (SB) 21-175 in 2021 and updated by House Bill (HB) 23-1225
- Created a review board within the Division of Insurance
- Goal: identify drugs costly to Coloradans, evaluate their impact, and determine if they are affordable in order to reduce prescription drug costs to patients
- If a drug is determined to be unaffordable, an upper pay limit may be set

# PDAB/PDACC



- Prescription Drug Affordability Board (PDAB)
  - 5 members
  - Identifies the drugs for review, performs the affordability review, places upper payment limit if drug determined to be unaffordable
- Prescription Drug Affordability Advisory Council (PDAAC)
  - 15 members appointed by PDAB
  - Provide stakeholder input on affordability

# PDAB Review Process





# PDAB Drug Selection

- 25 drugs initially recommended for reimbursement caps in 2023
- Hematology/Oncology Drugs
  - Emicizumab (Hemophilia A)
  - Ibrutinib (Chronic Lymphocytic Leukemia)
  - Osimertinib (EGFR Non-Small Cell Lung Cancer)
  - Dasatinib (Chronic Myeloid Leukemia)
  - Apalutamide (Prostate Cancer)
  - Ruxolitinib (Polycythemia Ver, Myelofibrosis, Graft versus Host Disease)
  - Pembrolizumab (multiple cancers)
  - Venetoclax (Acute Myeloid Leukemia, Chronic Lymphocytic Leukemia)



# PDAB Drug Selection

- 5 drugs from the list selected for affordability review<sup>1</sup>
  - Trikafta (cystic fibrosis): affordable
  - Enbrel (rheumatologic conditions): unaffordable
  - Genvoya (HIV): affordable
  - Cosentyx (rheumatologic conditions): pending review
  - Stelara (psoriatic disease, IBD): pending review

# PDAB Summary

- PDAB was passed in 2021 to help reduce prescription drug costs and is currently in the process of reviewing its first drugs for affordability.
- The first five drugs selected from the list were not oncology drugs, 2 have been deemed affordable, 1 unaffordable, and 2 remain under review.
- As several oncology drugs were eligible for review, it is expected that an oncology drug will likely be selected during the next affordability review.
- While a drug has been selected to have an upper payment limit set, the upper payment limit has not yet been determined and it is unclear how an upper payment limit will impact insurance coverage and healthcare facility formularies.

SB 24-124  
Healthcare Coverage  
for Biomarker Testing



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# Biomarker Testing

- “An analysis of a patient’s tissue, blood, or other biospecimen for the presence of an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention.”<sup>1</sup>
- Numerous targetable biomarkers: EGFR, HER2, BRAF, PDL1, MSI, etc



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# Targeted Therapies

- Targeted therapies improve survival for patients with targetable biomarkers:
  - EGFR+ Non-small Cell Lung Cancer<sup>1</sup>
  - HER2+ Breast Cancer<sup>2</sup>
  - Microsatellite Unstable Colon Cancer<sup>3</sup>
- Delays in starting targeted therapy in non-small cell lung cancer leads to lower survival<sup>4</sup>



1. Thai AA, Solomon BJ, Sequist LV, et al. Lung Cancer. *Lancet*. 2021; 398:535-554.  
2. Baselga J, Cortes J, Kim SB, et al. Pertuzumab plus Trastuzumab plus Docetaxel for Metastatic Breast Cancer. *NEJM*. 2012; 366:109-119. Accessed May 1, 2024. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1113216>  
3. Andre K, Shiu K, Kim TW, et al. Pembrolizumab in Microsatellite-Instability-High Advanced Colorectal Cancer. *NEJM*. 2020; 383:2207-2018.  
4. Scott JA, Lennerz J, Johnson ML, et al. Compromised Outcomes in Stage IV Non-Small-Cell Lung Cancer with Actionable Mutations Initially Treated Without Tyrosine Kinase Inhibitors: A Retrospective Analysis of Real-World Data. *JCO Oncol Pract*. 2023; 00:1-9. Accessed December 6, 2023.



# Biomarker Insurance Coverage

- 71% of insurance plans are more restrictive than the NCCN guidelines for biomarker testing coverage<sup>1</sup>
- 29% of patients report they didn't do biomarker testing because it wasn't covered by insurance or out-of-pocket costs were unaffordable<sup>2</sup>
- In patients with non-small cell lung cancer or colon cancer, patients who were older, black, or on Medicaid were less likely to receive biomarker testing than younger, white, or commercially insured patients<sup>3,4</sup>

1. Wong WB, Anina D, Lin CW, et al. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. *Per.Med.* 2022; 19(3): 171-180. Accessed May 1, 2024. <https://pubmed.ncbi.nlm.nih.gov/35118882/>.

2. American Cancer Society Cancer Action Network. Survivor Views: Biomarker Testing Survey Findings Summary. Published September 28, 2020. Accessed May 1, 2024.

<https://www.fightcancer.org/sites/default/files/Survivor%20Views%20Biomarker%20Testing%20Polling%20Memo.pdf>

3. Presley CJ, Soulos PR, Chiang AC, et al. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *JCO.* 2017;35(15): suppl6563. Accessed May 1, 2024. [https://ascopubs.org/doi/10.1200/JCO.2017.35.15\\_suppl.6563](https://ascopubs.org/doi/10.1200/JCO.2017.35.15_suppl.6563)

4. Lamba N and Iorgulescu B. Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer. *Cancer Epidemiol Biomarkers Prev.* 2020; 29 (12\_Supplement): PO-091. Accessed May 1, 2024. [https://aacrjournals.org/cebpa/article/29/12\\_Supplement/PO-091/181511/Abstract-PO-091-Disparities-in-microsatellite](https://aacrjournals.org/cebpa/article/29/12_Supplement/PO-091/181511/Abstract-PO-091-Disparities-in-microsatellite)



# SB 24-124

- Requires biomarker testing coverage for all large employer health benefit plans
- Biomarker testing is subject to the health plan's annual deductibles, copayments, or coinsurance
- Requires medical assistance programs to have a clear, accessible appeals process if biomarker testing is denied



# SB 24-124

- Passed in the Senate
- Currently in the House





**HB 24-1010**  
**Insurance Coverage for**  
**Provider-Administered Drugs**



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# White Bagging

- An insurance policy that a specialty drug is delivered to a healthcare facility or physician's office from a specific outside specialty pharmacy that is preferred by the insurance company.
- Goal is to reduce healthcare/drug costs



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# Oncology Concerns with White Bagging

- Unable to change the dose if needed on the day of administration, leading to potential delays in treatment
- Administration of the drug is dependent on arrival of the drug, if arrival is delayed it could delay patient treatment
- The oncology department cannot vouch for the integrity of the product sent to them
- Excessive waste if the drug is unable to be used



# HB 24-1010

- Prohibits carriers from requiring a provider-administered drug to be dispensed by a carrier specific specialty pharmacy. Patients can still opt to use the carrier pharmacy.
- Prohibits carriers charging additional fees/copayments if the provider administered drug was dispensed by a pharmacy other than the specific specialty pharmacy.



# HB 24-1010

- Passed in the House
- Currently in the senate





**HB 24-1149**  
**Modifications to Requirements for Prior  
Authorization of Benefits under Health  
Benefit Plans**



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# Prior Authorization (PA)

- “Approval from a health plan that may be required before you get a service or fill a prescription in order for the service or prescription to be covered by your plan.”<sup>1</sup>
- Used by health plans with the intention of reducing unnecessary treatments and reducing health costs.



1. Healthcare.gov Glossary. Prior Authorization. Accessed May 1, 2024. <https://www.healthcare.gov/glossary/prior-authorization/#:~:text=Approval%20from%20a%20health%20plan,be%20covered%20by%20your%20plan.>

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# Prior Authorization Issues

- Physician Concerns<sup>1</sup>:
  - 94% of physicians report delayed patient care due to PA
  - 80% report that PA can lead to patient abandoning treatment
  - 33% report that a PA has led to a serious adverse event to a patient, 19% to a life threatening event
- Patient Concerns<sup>2</sup>:
  - 37% of patients report delayed/missed care due to PA
- Healthcare Inequity
  - Women, patients with disabilities, and those in poverty are more likely to experience delays related to PA and other administrative tasks<sup>2</sup>
  - Hispanic or black patients with chronic disease experience PA denial rates 20-40% higher than white patients<sup>3</sup>



1. American Medical Association (AMA). 2022 AMA Prior Authorization Physician Survey. Accessed May 1, 2024. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

2. Kyle MA and Frakt AB. Patient administrative burden in the US health care system. *Health Serv Res.* 2021; Oct; 56(5): 755-765. Accessed May 1, 2024. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8522562/>.

3. Institute for Patient Access. Health Disparities & Medication Access. Published Dec 2022. Accessed May 1, 2024. [https://instituteforpatientaccess.org/wp-content/uploads/2022/12/IfPA\\_HealthDisparitiesReport\\_Dec-2022.pdf](https://instituteforpatientaccess.org/wp-content/uploads/2022/12/IfPA_HealthDisparitiesReport_Dec-2022.pdf)

# HB 24-1149

- Requires carriers to handle PA interactions through its interface/electronic transmission system if a provider utilizes the system
- Limits PA requirements to once every 3 years for an FDA approved chronic maintenance drug that has previously been approved
- Extends the duration of an approved PA for a service or prescription drug to a calendar year
- Requires carriers to post on their public website information regarding their PA requests, approval/denial data, exemptions, and formularies



# HB 24-1149

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- Passed in the House and Senate
- Awaiting governor's signature





# Key Points

- PDAB is currently reviewing drugs for affordability and candidacy for an upper payment limit. An oncology drug is expected to be evaluated in the future. The implementation of upper payment limits is still to be determined.
- SB 24-124 works to increase insurance coverage of biomarker testing to enable patients to have greater access to the best cancer treatments available. Still awaiting house approval.
- HB 24-1010 prohibits insurance companies from requiring the use of a specific specialty pharmacy, allowing for patients to have greater choice in their medical care. Still awaiting Senate approval.
- HB 24-1010 restricts prior authorization use to allow for greater coverage of care for patients, to reduce delays in treatment, and to provide greater transparency to the public of insurance prior authorization practices. Bill passed, awaiting governor's signature to become law.

# References

- American Cancer Society Cancer Action Network. Survivor Views: Biomarker Testing Survey Findings Summary. Published September 28, 2020. Accessed May 1, 2024.
- American Medical Association (AMA). 2022 AMA Prior Authorization Physician Survey. Accessed May 1, 2024. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>.
- Andre K, Shiu K, Kim TW, et al. Pembrolizumab in Microsatellite-Instability-High Advanced Colorectal Cancer. *NEJM*. 2020; 383:2207-2018.
- Baselga J, Cortes J, Kim SB, et al. Pertuzumab plus Trastuzumab plus Docetaxel for Metastatic Breast Cancer. *NEJM*. 2012; 366:109-119. Accessed May 1, 2024. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1113216>
- Colorado Department of Regulatory Agencies. Colorado Prescription Drug Affordability Review Board and Advisory Council. Accessed April 26, 2024. <https://doi.colorado.gov/insuranceproducts/health-insurance/prescription-drug-affordability-review-board>.
- Colorado General Assembly. Healthcare Coverage for Biomarker Testing. Accessed May 1, 2024. <https://leg.colorado.gov/bills/sb24-124>.
- Colorado General Assembly. Insurance Coverage for Provider-Administered Drugs.. Accessed May 1, 2024. <https://leg.colorado.gov/bills/hb24-1010>.
- Colorado General Assembly. Prior Authorization Requirements Alternatives. Accessed May 1, 2024. <https://leg.colorado.gov/bills/hb24-1149>.
- Healthcare.gov Glossary. Prior Authorization. Accessed May 1, 2024. <https://www.healthcare.gov/glossary/prior-authorization/#:~:text=Approval%20from%20a%20health%20plan,be%20covered%20by%20your%20plan>.
- Institute for Patient Access. Health Disparities & Medication Access. Published Dec 2022. Accessed May 1, 2024. [https://instituteforpatientaccess.org/wp-content/uploads/2022/12/IfPA\\_HealthDisparitiesReport\\_Dec-2022.pdf](https://instituteforpatientaccess.org/wp-content/uploads/2022/12/IfPA_HealthDisparitiesReport_Dec-2022.pdf).
- Lamba N and Iorgulescu B. Disparities in microsatellite instability/mismatch repair biomarker testing for patients with advanced colorectal cancer. *Cancer Epidemiol Biomarkers Prev*. 2020; 29 (12\_Supplement): PO-091. Accessed May 1, 2024. [https://aacrjournals.org/cebp/article/29/12\\_Supplement/PO-091/181511/Abstract-PO-091-Disparities-in-microsatellite](https://aacrjournals.org/cebp/article/29/12_Supplement/PO-091/181511/Abstract-PO-091-Disparities-in-microsatellite)
- Kyle MA and Frakt AB. Patient administrative burden in the US health care system. *Health Serv Res*. 2021; Oct; 56(5): 755-765. Accessed May 1, 2024. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8522562/>.
- Presley CJ, Soulos PR, Chiang AC, et al. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *JCO*. 2017;35(15): suppl6563. Accessed May 1, 2024. [https://ascopubs.org/doi/10.1200/JCO.2017.35.15\\_suppl.6563](https://ascopubs.org/doi/10.1200/JCO.2017.35.15_suppl.6563)
- Thai AA, Solomon BJ, Sequist LV, et al. Lung Cancer. *Lancet*. 2021; 398:535-554.
- Scott JA, Lennerz J, Johnson ML, et al. Compromised Outcomes in Stage IV Non-Small-Cell Lung Cancer with Actionable Mutations Initially Treated Without Tyrosine Kinase Inhibitors: A Retrospective Analysis of Real-World Data. *JCO Oncol Pract*. 2023; 00:1-9. Accessed December 6, 2023.
- Wong WB, Anina D, Lin CW, et al. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. *Per.Med*. 2022; 19(3): 171-180. Accessed May 1, 2024. <https://pubmed.ncbi.nlm.nih.gov/35118882/>.

Questions?

