

Oncology Learning Collaborative

Session #3:
Diagnosis, 2nd Opinion,
Precision Medicine/Biomarkers
& Treatment

Friday November 17, 2023



Today's Team



Sandra Morris, Moderator
Principal

**About Quality
Benefits Design, LLC**



Cheryl Larson
President & CEO

MBGH



Karen van Caulil
President & CEO

**Florida Alliance for
Healthcare Value**

Your Role in Today's Program

Use Chat for:

- Comments or questions
 - Technical or logistical issues
 - You can also use "Raise Hand"
-

For those on the phone:

- **Mute or Unmute using *6**

Participate in the
Polling Questions
during this program

&

Complete the
evaluation at the end
of today's program

See link in chat now!

Please respond to our last webinar evaluation

We are dropping the link into the chat now for the survey from our second session in October



Thank you to our
generous sponsors!



Key Areas of Project Focus

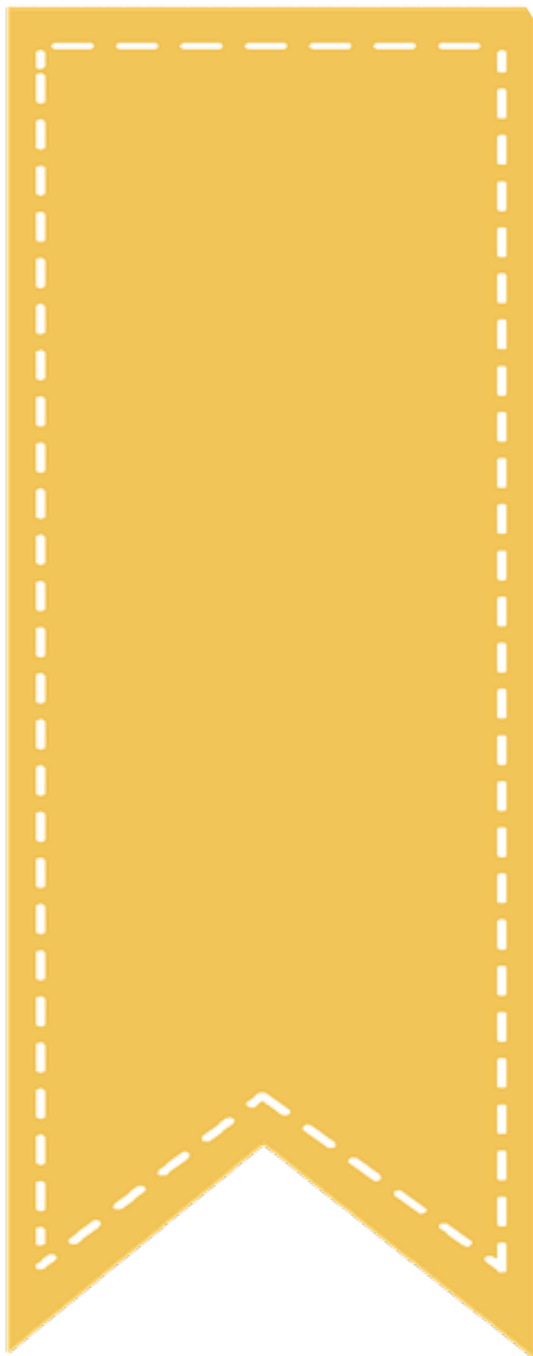
- Prevention and Screening
- Testing and Diagnosis – Early and Correct Diagnosis
- Early Access to Navigation – Needed Support and Guidance
- Correct Treatment at the Right Place – including Palliative Care, Hospice/End of Life Care
- Survivorship/Return to Work



- Pharmacy/Specialty Pharmacy Management – *Right Drug, Right Patient, Right Price*
- Coverage of Precision Medicine/Biomarker Testing


Oncology Learning Collaborative

1. September 19, 9:30-11:00AM CT; 10:30-12:00 ET – *Prevention, Screening/Testing, Early Identification & Site of Care*
2. October 17, 1:00-2:30PM CT; 2:00-3:30PM CT – *Navigation, Psychosocial Support, Survivorship & Return to Work*
3. November 17, 1:00-2:30PM CT; 2:00-3:30PM CT – *Diagnosis, 2nd Opinion, Precision Medicine/Biomarkers & Treatment*
4. December 8, 2:30-4:00PM CT; 3:30-5:00PM CT – *Employer Insights & Guide to Oncology Management*



Please Bookmark this webpage to
view all the resources, including
webinar recording, slides and
summaries of program content

[Florida Alliance & MBGH:](#)
[Oncology Learning Collaborative](#)



Cancer has become more complex and challenging ...

- Rapidly expanding diagnostic testing and treatments with updates to health plan coverage not always keeping pace.
- Wide variations in oncology care across settings and programs.
- Reimbursement challenges with increased billing errors, denied claims needing appeals, prior authorizations delaying care.
- Fragmented, siloed healthcare system with poor communication linkages between stakeholders.

Cancer Diagnosis:

Some Long-Standing Strategies
Are Still Used and Often Required
Prior to Approval of Newer
Strategies

- Biopsy
- Bone Scan
- Complete Blood Count
- CT Scan
- Circulating Tumor Markers
- Cytogenic Analysis
- Immunophenotyping
- MRI
- Nuclear Scan
- PET Scan
- Ultrasound
- Urine Cytology
- X-rays





Leading-Edge Diagnostics

- Biomarker Testing
- Artificial Intelligence
- Second Opinion Programs

Biomarker Testing

- Biomarkers: substances such as proteins and genes found in blood, body fluids, or tissues
- Useful in diagnosis of:
 - Type of cancer
 - Staging level of growth, targeting the therapy that will have the best outcome for an individual patient
 - Measuring whether the treatment is working, or cancer is returning
- Allows oncologists to practice precision medicine

Biomarker Testing & Rare Cancers

Biomarker testing is especially important for patients with rare cancers or those that have few treatment options, because mutations found in different cancers may overlap. If a person has a rare cancer with a mutation seen in other cancers, there may be a treatment that could potentially work in effectively treating the rare cancer as well.

Polling Question

1. Does your plan include coverage for expert guideline recommended cancer biomarker testing? (NCCN, ASCO, CAP)



Polling Question

2. If yes, is prior authorization required for coverage?



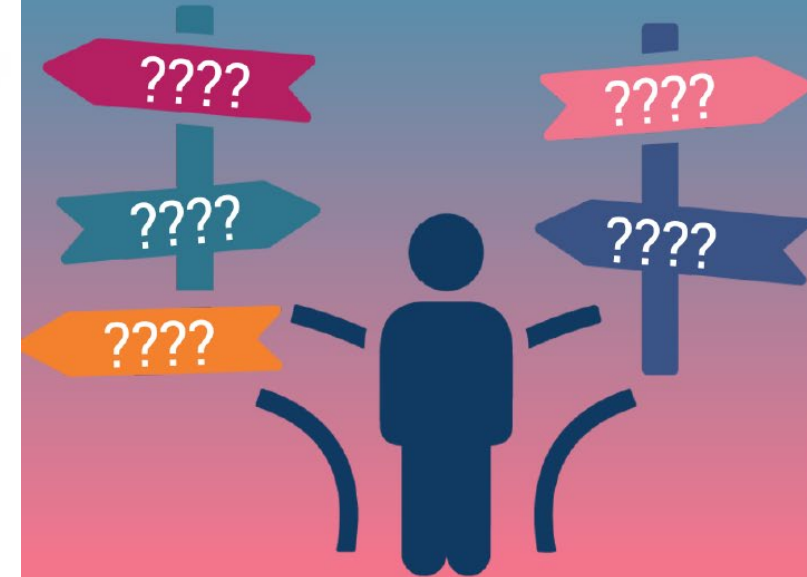
Polling Question

3. Is your plan real-time updated as new guidelines and FDA-approved biomarker tests are available?



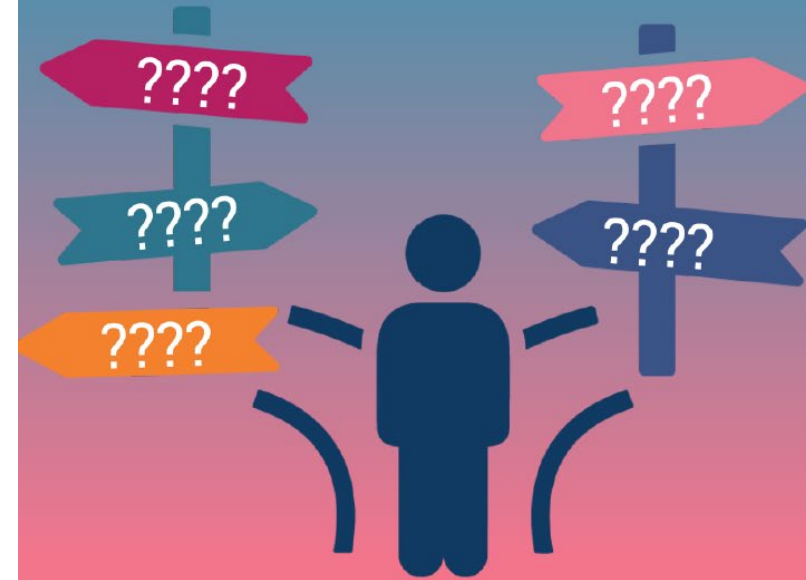
Questions to Ask Your Medical Carriers

- Does your plan cover biomarker testing to determine a patient's potential clinical trial eligibility?
- If no in-network providers/labs can perform a specific biometric test, does your plan waive the out-of-network financial penalty to the member?
- Does your plan cover biomarker tests for diagnosis, treatment and on-going monitoring?
- What are the rates of approved prior authorizations for testing coverage and approved appeals when biomarker testing has initially been denied?



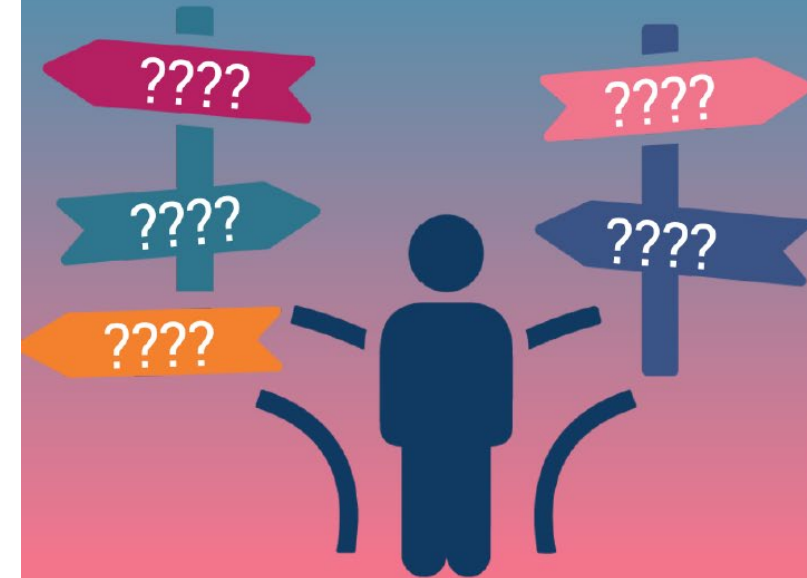
Employer Action Steps

- Confirm with carriers that processes are in place to efficiently and proactively evaluate use of biomarker testing for diagnosis, treatment and ongoing monitoring.
- Determine whether carriers are consistently evaluating the biomarker testing market and implementing opportunities for savings with specific lab networks and/or proactive use of panel tests over single biomarker testing.
- Ensure that carrier call center reps are being provided frequently updated lists of biomarker tests that do and do not require prior authorization reviews for coverage. To avoid delays in care, make sure they understand the plan language and benefits procedures.



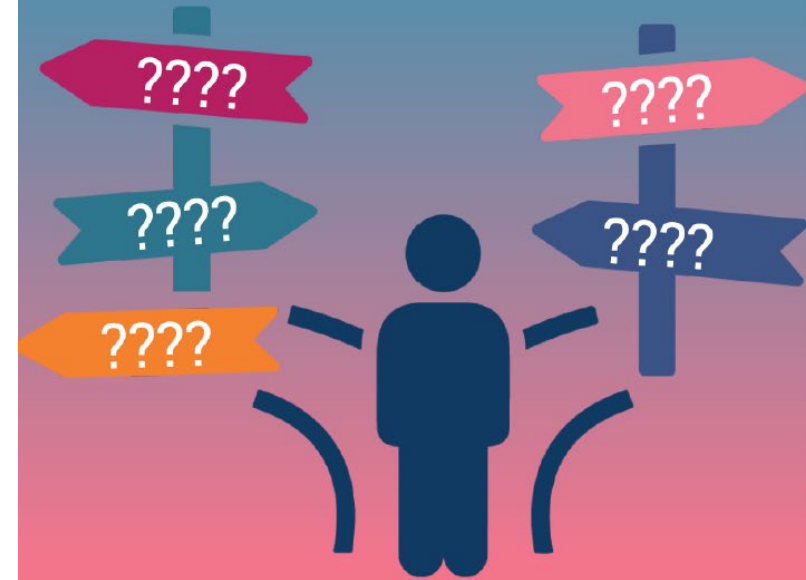
Employer Action Steps

- Recognize that some insurance plans will not cover the costs of biomarker tests and will deem them to be “experimental and investigational.” Confirm that:
 - Your plan has a strategy in place to ensure easily followed directions for appeal filing.
 - Biomarker testing coverage appeals are processed, and decisions communicated without long delays.
 - Appropriate clinical experts are involved in appeal reviews.
- Determine whether there is a need for a narrow network of biomarker testing facilities that have the skills and resources to properly manage patient cases and control the scope and costs of these tests.



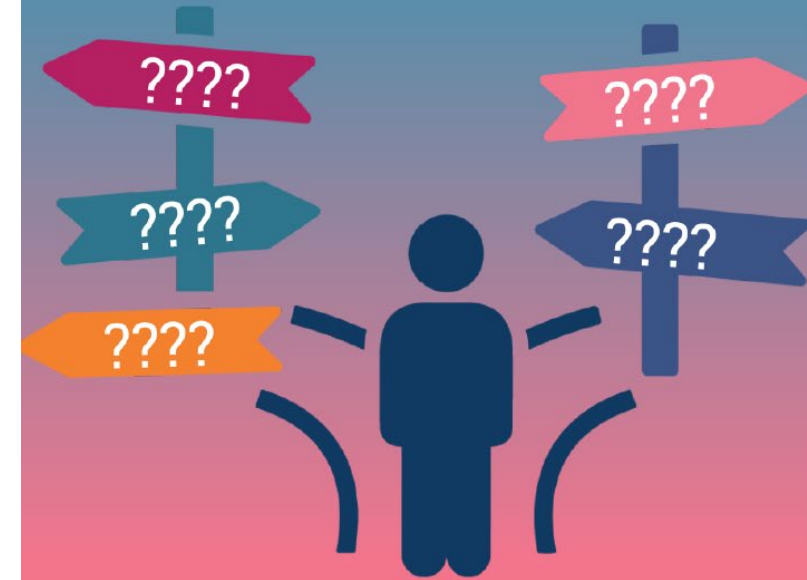
Employer Action Steps

- Check for outdated plan language to avoid overarching exclusions for genetic testing; language should be modified to assure coverage for appropriate use achieved through language that alerts members and call center reps to check for prior authorization requirements for coverage of testing.
- Ensure that plan design language sections concerning prior authorizations include specifics about any requirements around genetic/biomarker testing for diagnosis, treatment, and/or post treatment monitoring.



Employer Action Steps

- Consider implementing a member communication campaign to raise awareness of the value of biomarker testing and plan coverage of these tests.
 - [See Employer Articles for Use with Employees & Plan Members](#)
- Confirm plan coverage of all tests that are FDA-approved as companion diagnostics to match patients to all FDA-approved targeted therapies and immunotherapies.
- Allow prior authorization flexibility through use of broad-based plan coverage language: “Genetic/ Biomarker Testing for diagnosis, treatment, and/or post treatment monitoring, as approved by the Plan.”



Essential Resources for Biomarker Testing

- MBGH – [Biomarker Testing: What It Is and Why Employers Should Invest In It](#)
- CancerCare – [Employers' Prescription for Employee Protection Toolkit: Best Practices for Biomarker Testing Coverage](#)



Use of Artificial Intelligence (AI) to Diagnose and Treat Cancer



- Artificial intelligence (AI): Computer programs or algorithms that use data to make decisions or predictions
- Intent is not to use it to disregard human expertise, but rather to assist physicians in making decisions about diagnosis and treatment
- Can analyze medical images with significant accuracy that the naked eye may not see, reducing false negatives, and aiding correct diagnoses
- Has been used for over 20 years to analyze mammograms and is now being used to diagnose and treat cancers often missed in early stages and hard to recognize with the naked eye like pancreatic, prostate, lung and skin
- Select AI systems have been covered on a per use basis by some payers since 2020, but there is concern that per use AI reimbursement may result in overuse. Alternative reimbursement approaches are being developed such as outcome-based payments.



1. SmartLinQ™ – When an oncology practice participates in this program, information about their patients is transferred into a platform where the data is used to help inform diagnoses and care decisions.
2. MIT and Mass General Cancer Center – AI program Sybil was trained on low-dose chest computed tomography scans, for those between ages 50 and 80 who either have a significant history of smoking or currently smoke.
 - For patients undergoing screening for lung cancer, Sybil was able to look at an image and accurately predict the risk of a patient developing lung cancer within six years.



Directives on AI

Executive Order – 10-30-23

HHS AI Task Force – For the development of a strategic plan with appropriate guidance to include policies and frameworks with integrated regulations as needed. Focus will be on responsibly deploying and using AI and AI-enabled technologies in the health and human services sector, spanning research and discovery, drug and device safety, healthcare delivery and financing, and public health.

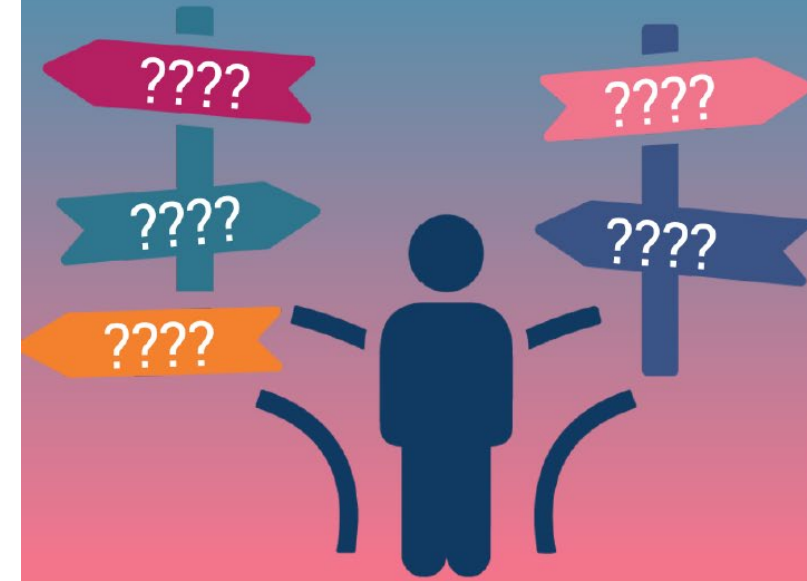
AI Equity – There will be active monitoring of the performance of algorithms to check for discrimination and bias in existing models to identify and mitigate any discrimination and bias in current systems.

AI Security – Mandated integration of safety, privacy, and security standards throughout the software development lifecycle, with a specific aim to protect personally identifiable information.

AI Oversight – To ensure appropriate human oversight over the application of AI-generated output from the development, maintenance, and utilization of predictive and generative AI-enabled technologies in healthcare delivery and financing.

Questions to Ask Your Medical Carriers

- Does your plan cover use of artificial intelligence programs?
- If yes, is prior authorization required for coverage?



Use of Expert Second Opinion Programs

Provide peace of mind that diagnoses are accurate and treatment plans are comprehensive, given the rapidly advancing technology of cancer care.

Especially helpful with rare or very complicated cases of cancer as the opinions typically come from centers of excellence with more advanced technology, more experienced oncologists, cutting edge treatments, and access to clinical trials.

Programs may be provided by the medical plan carrier or through third party vendors.

Evaluating Second Opinion Programs

Look for programs that:

Provide actual engagement rates from current customers, the percentage of cases where the second opinion resulted in changes in diagnosis or treatment plan, and criteria used to determine it was a change

Make it easy for a member to use the program – one call does it all

Provide one point of contact for the member who helps them navigate through the process and answers their questions.

Provide post-opinion discussions of results for member and treating physician.

Have flexible pricing strategies PEPM or per case administrative costs

Other recommended criteria based on your experiences?

A detailed microscopic image of several red blood cells, showing their characteristic biconcave disc shape and reddish-pink color. The cells are in focus, with some appearing more prominent than others.

Recent Advances in Cancer Treatment

Stem Cell Transplants: The administration of stem cells previously removed from the patient or another person to grow new white and red blood cells and platelets to replace those destroyed by cancer, radiation or chemotherapy

Rapidly advancing technology but still very risky for the patient

[American Cancer Society – Questions Patients Should Ask](#)

Recent Advances in Cancer Treatment

Immunotherapy: The use of biologics (made from living organisms) to improve the immune system's ability to fight cancer cells.

6 major categories (discussed in more detail in the employer guide):

- Immune Checkpoint Inhibitors
- T-Cell Transfer Therapy (CAR T-cell Therapy)
- Monoclonal Antibodies
- Cancer Vaccines
- Immune System Modulators
- Photodynamic Therapy

Note: Immunotherapy is typically already covered by employer health plans, but it is worth it to have discussions with your carriers to see if any restrictions are in place that would significantly delay member access to these treatments.

A detailed microscopic image of several red blood cells, showing their characteristic biconcave disc shape and reddish-pink color. The cells are clustered together, with some in sharp focus and others blurred in the background.

Recent Advances in Cancer Treatment

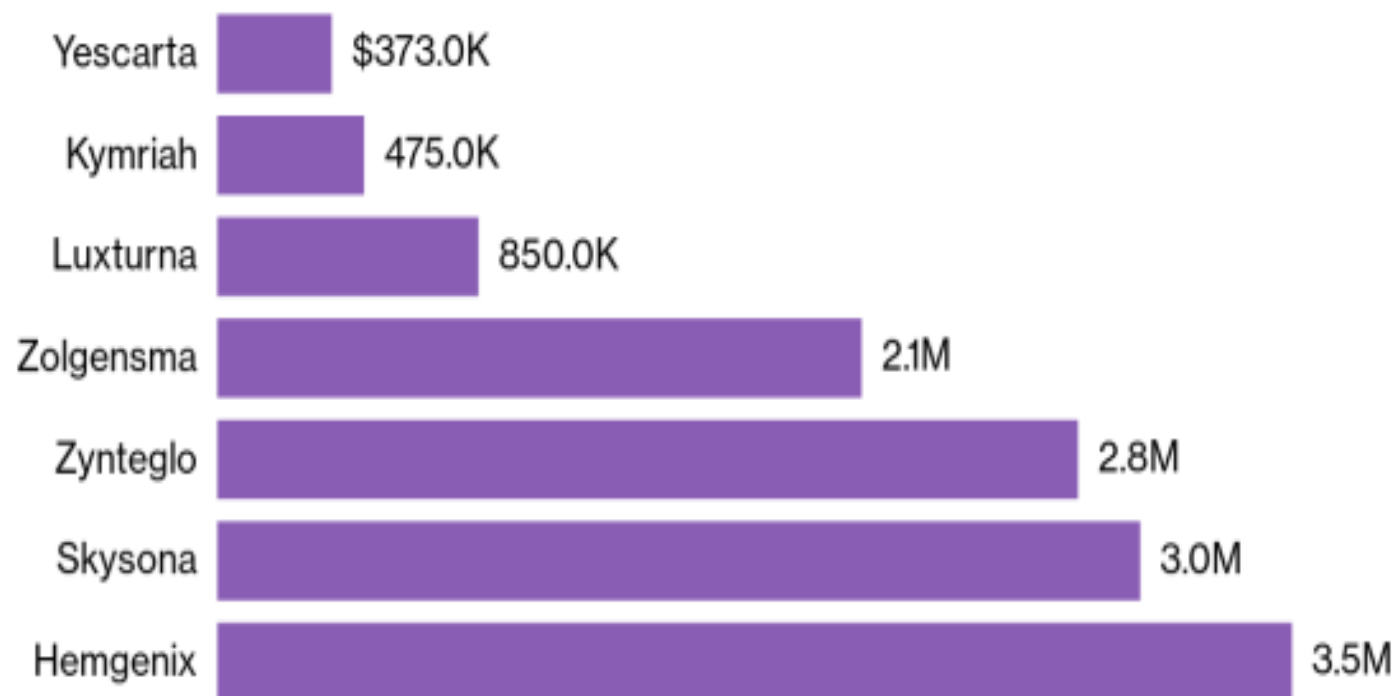
Targeted cell and gene therapies: A type of precision medicine that uses biomarker testing to identify targeted growth proteins and enzymes in cancer cells that can be destroyed through use of small (able to enter cancer cells) or large (destroy the outside cancer cell walls) molecule drugs taken orally, or monoclonal antibodies administered intravenously.

Paying for Cell and Gene Therapies

Prices of FDA-Approved Gene Therapies

Hemgenix cost surpasses previous record

■ Cost Per Dose or Course



Sources: Novartis AG; Gilead Sciences, Inc.; Spark Therapeutics; Bluebird Bio Inc.; CSL Behring

Note: The FDA approved Skysona under the accelerated pathway, under the condition Bluebird will provide long-term data confirming the treatment's benefit.

A close-up, blurred image of a pen writing on a document. The document features a line graph with a dotted trend line and a solid line showing fluctuations. The pen is positioned at the top right, and the overall image has a blue-tinted, out-of-focus aesthetic.

The Future is Uncertain

- The costs of just a couple of claims could bankrupt a self-insured employer, while fully insured ones will see substantial premium increases
- While stop-loss insurance is still being used by some employers, the insurance typically has limits well below costs of cell and gene therapies. As these therapies become available for treating more commonly occurring diseases, the insurance costs will most likely overshadow the risks of not having it.
- Employers may force federal intervention by excluding coverage for multimillion dollar therapies, limiting first-dollar primary coverage to employees only, or replacing their healthcare insurance benefits with employee payments to purchase external insurance.

Employer Call to Action

Employer Invite to Florida Alliance Webinar

November 21, 2023

10-11 AM CT • 11:00-12 PM ET

Contact Karen van Caulil - karen@flhealthvalue.org
if you would like to attend.

- What are Cell and Gene Therapies and their value?
- What are key needs for patient access to CGTs?
- What are key market factors driving the need for an affordable CGT solution?
- Why did the Jacksonville Police Officers and Firefighters Health Insurance Trust decide to provide coverage for CGTs?

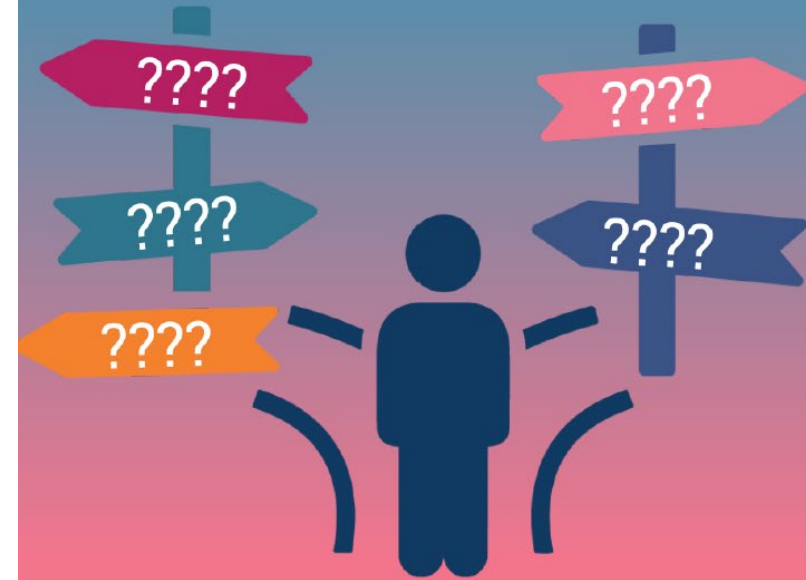
We have [issued a call for employers](#) to take action to address how best to provide their members with affordable access to cell and gene therapies.

Members are interested in conducting a feasibility study to determine if piloting a national risk pool for coverage of some of the highest cost therapies, starting with rare and orphan diseases, would work. This would greatly benefit employers as plan sponsors and fiduciaries.

Employers are already at risk for a whole new magnitude of benefits expenses. Not acting now could lead to the demise of employer-sponsored healthcare benefits as we know them.

Questions to Ask Your Medical Carriers

- Is prior authorization required for coverage of cell and gene therapies?
- Is biomarker testing required when appropriate for cell and gene therapies to be approved for coverage?
- What are the rates of approved prior authorizations for coverage and appeals when coverage of cell and gene therapies is initially denied?





Use of Copay Accumulators, Maximizers and Alternative Funding Programs

Cancer care involving prescription drugs typically falls within the top five most costly health care benefits areas for employers and sends them scrambling for ready-made solutions to lower the costs.

- To help the uninsured, underinsured, and low-income patients access high-cost therapies, prescription drug manufacturers established patient assistance programs (PAPs).
- As plan fiduciaries, employers worried that PAPs were interfering with their abilities to prudently manage plan assets and were equally concerned that falsely calculated employee cost shares for PAP participants predisposed them to claims of discriminatory plan management from members of specific disease states who were not privy to the PAPs.
- Employers were compelled to require PBMs and medical carriers to develop processes to track PAP payments for covered members to prevent them from being falsely counted as employee cost share.



Use of Copay Accumulators, Maximizers and Alternative Funding Programs

- **Accumulator Programs** – PAPs provide a capped dollar amount per patient that is not applied to patient's deductible/OOP Max. Once PAP is exhausted, the patient becomes responsible for total payment until deductible is met, followed by copays or coinsurance until their maximum out-of-pocket limit is met.
- **Maximizer Programs** – A capped amount of PAP funding is divided equally over the expected length of treatment months, thus reducing, or eliminating the patient's cost share obligations.
- **Alternative Funding Programs** – Specific high-cost drugs are eliminated from an employer's plan coverage, covered only when PAP assistance has been denied, or designated as Non-Essential Health Benefits (Non-EHB); making essentially all plan members eligible to apply for PAP assistance.

Polling Question

1. Does your plan include a copay accumulator program?



Polling Question

2. If yes, has your claims administrator contacted you concerning September 2023 legislation that limits which drug claims your accumulator can be applied to?



Polling Question

3. Does your plan include a copay maximizer program?



Polling Question

4. If yes, do you believe the copay maximizer program has helped members adhere to treatment in the long run after PAP assistance is exhausted?



Recent Legislation

- Laws [in 20 states and Puerto Rico address the use of copay adjustment programs by insurers or PBMs by requiring any payment or discount made by or on behalf of the patient be applied to a consumer's annual out-of-pocket cost-sharing requirement.](#)
- On a federal level, [S.1375-HELP Copays Act](#) and [H.R.830-HELP Copays Act](#) were introduced to the 118th Congress, with both bills requiring health plans to apply third-party payments, financial assistance, discounts, product vouchers, and other reductions in patient's out-of-pocket drug expenses toward their cost share limits.
- September 29, 2023, the [U.S. District Court for the District of Columbia struck down a previous administrative rule](#) that allowed health insurers to not count drug manufacturers' copay assistance toward a patient's out-of-pocket costs. This makes insurers unable to use copay accumulators for drugs without generic equivalents, thus allowing assistance to be counted as cost-sharing for those drugs. [Federal Court Strikes Down HHS Rule on Copay Accumulator Programs | Maynard Nexsen - JDSupra](#)



Alternative Funding Programs (AFPs): Friend or Foe?

- When PAPs run out of funding, patients abandon therapies with the benefits of improved treatment outcomes for patients/employers being lost along with sales profits for drug manufacturers and PBMs.
- These outcomes resulted in alternate funding programs (AFPs) that promise affordable patient access and significant cost avoidance for adopting employers.
- The patient is directed to enroll in a vendor administrated AFP that typically uses a co-pay maximizer approach to assist them to access PAP funding.
- Patients pay little or no money for their drugs and employers avoid paying all or most of the drug costs.



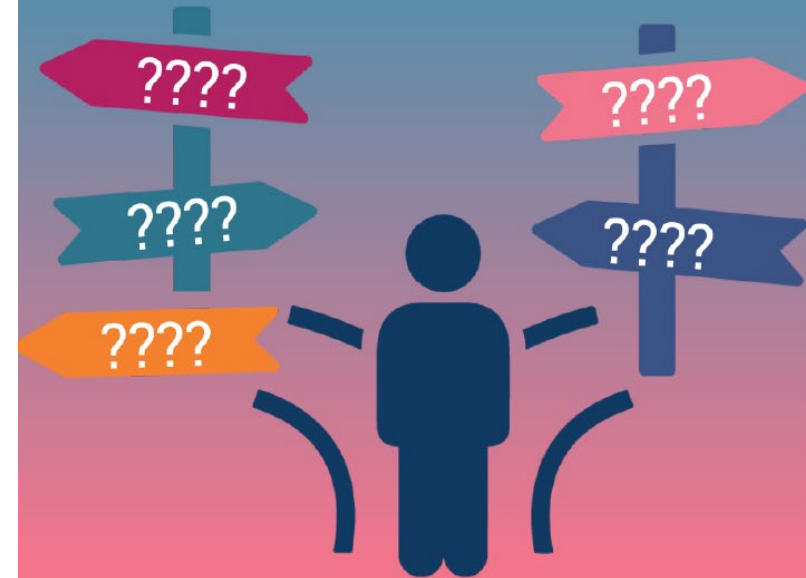
Employers Using AFPs Should Seek Legal Input

- Employers should carefully evaluate associations with AFPs as issues concerning ERISA and IRS compliance are coming into play. For example, as outlined by [VIVIO](#), use of funds involving employee premiums to pay AFP administrative expenses may constitute breach of fiduciary responsibilities under ERISA.
- Even if AFPs limit procurement of PAP funding to lower income participants, plan benefits may become skewed toward highly compensated employees leading to tax code violations without taxation of these employees.
- MBGH Employer Action Brief: Copay Accumulators, Copay Maximizers and Alternate Payment Programs: Friends or Foes?



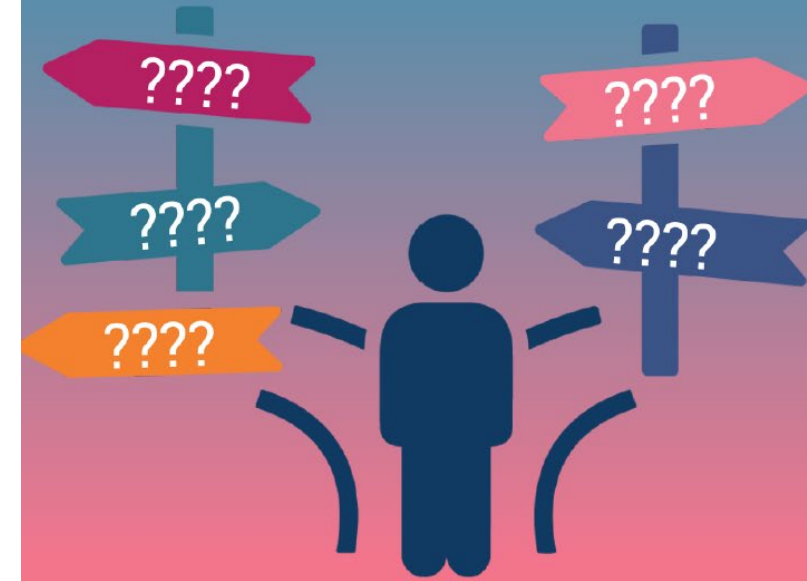
Employer Action Steps

- Involve legal, employee relations, employee, and risk reduction representatives in the decision-making process.
- Ensure cost savings analyses include disclosed administrative fees and as well as nondisclosed factors such as loss of rebates and patient cost share contributions, changes in network discounts based on sales volumes, fees related to communication of plan changes, etc.
- Seek input from employers with long-term experience using programs and vendors.
- Stay abreast of recent and pending lawsuits and legislation related to programs and vendors.
- Seek stakeholder (members, insurance carriers, etc.) input concerning the value of programs and vendors.



Employer Request

Are there any employers who would like to share their experience, insights, initiatives, etc. on copay accumulator, maximizer, or alternative funding programs with us right now?





Supporting Clinical Trials

- [The National Cancer Institute \(NIH\)](#) provides help to interested participants and providers in locating clinical trials.
- While ACA requires coverage of routine costs associated with participation in clinical trials, there may be differences between carriers regarding routine costs.
- Examples of important questions to ask carriers:
 - What criteria are being used to determine which clinical trials are covered ([ACA requires approved trials to be federally approved or funded.](#))?
 - Are members limited to coverage [at specific phases of clinical trials](#) or [stages of cancer progression](#)?
 - What criteria are being used to determine if care is routine?
 - Is there a system in place for determining coverage for non-routine services?



Coverage of Experimental Care

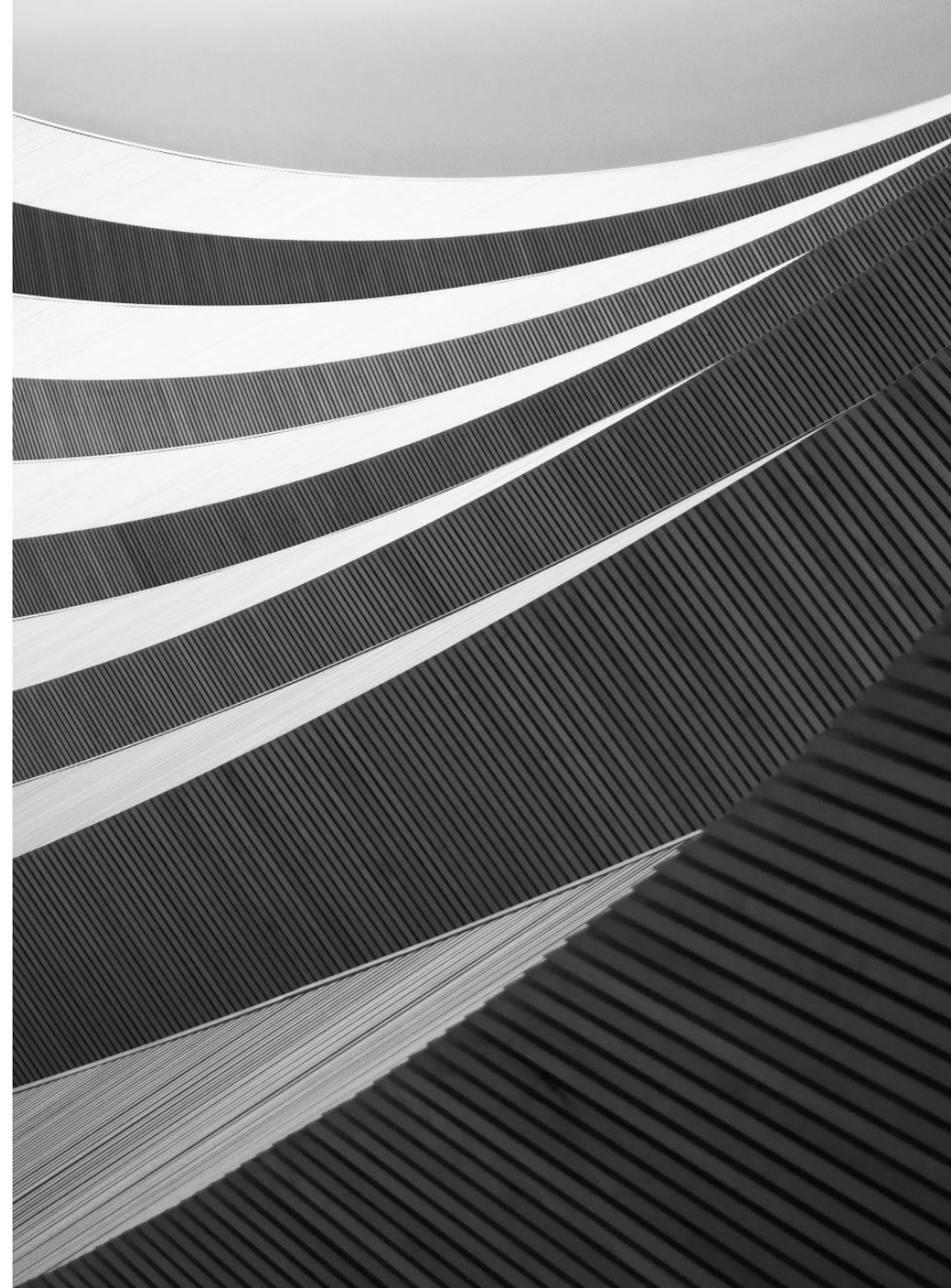
- Experimental cancer care: Any type of treatment that has not yet received approval from the Food and Drug Administration (FDA) for general use among the public.
- The 2018 Right to Try Act gives patients with life-threatening conditions who have exhausted approved treatment options, are not eligible for clinical trials, and have signed informed consent access to non-FDA approved treatments. It does not require employer or carrier coverage.
- The FDA has issued updated draft guidance on charging for experimental drugs but until finalized and federal law is passed to require coverage, patients will continue to be limited to care from sources that do not charge or charge affordable rates.

Coverage of Experimental Care

Some employers have riders to waive (as determined by the plan) experimental, not medically necessary, or investigational denials of service when treatments are supported by multiple sources of medical research, genetically based testing, or prior history of use with successful clinical outcomes.

Appropriate employer resources, i.e., human, legal, and employee relations leaders should review their current plan terms concerning coverage of experimental care and decide if they are comfortable with them as written and can defend them if challenged.

Also seek input from insurance carriers and regional employer health care coalitions concerning benchmarking to determine prevailing strategies among other employers.



Action Items from this call

- Please share your stories with Cheryl or Karen after today's call
- Project recording, slides and webinar summaries can be found here:
- [Florida Alliance & MBGH: Oncology Learning Collaborative](#)
- Save the Date – Final event December 8!

Complete the webinar survey now
– See chat!

Employer Insights & Guide to Oncology Management

December 8, 2023

- 2:30-4:00 PM CT
- 3:30-5:00 PM ET



Join us for the final webinar – a culmination of all project activities

- Employer panels sharing “pearls” and successes in oncology management
- Overview of Employer Guide & Insights to Oncology Management
- Access to vetted resources to support employer efforts
- Time for Q&A

Thank You!

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