Diagnosis, 2nd Opinion, Precision Medicine/Biomarkers & Treatment

November 17, 2023

Moderators

- Cheryl Larson, President & CEO, Midwest Business Group on Health
- Sandra Morris, Principal, About Quality Benefits Design, LLC (MBGH)
- Karen van Caulil, PhD, President and CEO, Florida Alliance for Healthcare Value

MBGH Employer Advisors

- Dan Dentzer, Manager: Health and Welfare Strategy, United Airlines
- Carole Mendoza, VP of Benefits, Voya Financial
- Sherri Samuels-Fuerst, VP, Total Rewards, Sargento Foods

Florida Alliance Employer Advisors

- Lea Ann Biafora, CEO/Founder of Professional Cancer Care Experience Advisors, Beacon Advocates
- Rosa Novo, Executive Benefits Director, Miami-Dade County Public Schools

Coalition Support

- John Butler, Project Management Consultant (MBGH)
- Lori Hurt, Director, Finance & Operations (MBGH)
- Allison Larsen, Manager, Events & Marketing (MBGH)
- David Cavalleri, PhD, Director of Quality Improvement, Florida Alliance
- Ashley Tait-Dinger, Vice President, Florida Alliance

Project Sponsors

- Genentech
- Merck
- Pfizer

Key Areas of Project Focus

Covered Previously:

- 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

Covering Today:

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

Oncology Learning Collaborative

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

Link to Project Resources

Locate additional information and project resources, including the webinar recordings and slide presentations, at Florida Alliance & MBGH: Oncology Learning Collaborative.

Diagnosis, 2nd Opinion, Precision Medicine/Biomarkers & Treatment (Sandra)

Cancer Has Become More Complex and Challenging

- Rapidly expanding diagnostic testing over the last five years and treatments with updates to health plan coverage are not always keeping pace.
- Wide variations in oncology care across settings and programs
- Reimbursement challenges are still there with increased billing errors because of the use of wrong codes, denied claims needing appeals, and 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. There are not a lot of barriers to getting these standard tests.
  - 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

- Has taken hold in the last few years and is one of the best things that could happen for someone who has developed cancer.
- 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, or
  - Measuring whether the treatment is working, or the cancer is returning. So testing is going to be a lifelong mechanism for the cancer patient.
- Allows oncologists to practice precision/personalized medicine.
- 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.
- Biomarker testing is an area that is growing on a daily basis.
- More than likely, your carriers are covering but with a lot of barriers in the way.

Polling Result – Question: Does your plan include coverage for expert guideline-recommended cancer biomarker testing? (NCCN, ASCO, CAP)

- Yes – 54% (7/13)
- No – 0% (0/13)
- Don't Know – 46% (6/13)

Polling Result – Question: If yes, is prior authorization required for coverage?

- Yes – 100% (6/6)
- No – 0% (0/6)
- Don't Know – 0% (0/6)

Polling Result – Question: Is your plan real-time updated as new guidelines and FDA-approved biomarker tests are available?

- Yes – 20% (1/5)
- No – 40% (2/5)
- Don't Know – 40% (2/5)

Questions to Ask Your Medical Carriers

- Does the 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 ongoing monitoring?

- What are the rates of approved prior authorizations for testing and approved appeals when biomarker testing has initially been denied?

Comments

Sandra

- You pay your carrier for prior authorization. It is an oncologist who is ordering the biomarker testing and they are not going to order testing that is not necessary. Prior authorizations are barriers when it comes to oncology treatments. This is why you need to ask your carrier about the rate of approval on the initial and appealed requests and you probably will find that rate of approval to be extremely high. The recommendation is to remove prior authorization.
- Don't charge a penalty if the lab that has to perform a specific biomarker test is not in the network. If you do, you may be imposing a financial barrier.
- Make sure you cover for diagnosis, treatment, and ongoing maintenance. Maintenance is important to pick up when cancer may be returning.

Comments

- We do have the testing in our plan. They don't require a PA. Some do go through an appeals process. Insurance carriers will push back by saying there are so many of them with so many codes that it is hard to manage. Has anyone else gotten this pushback? (Miami-Dade County Public Schools)
- You are correct, but the guidelines are very clear on which are appropriate and when. (Sandra)
- Hold your carriers accountable. Know how many tests they are doing, denying, or denying multiple times and then approving. Pay attention to the reporting. (United Airlines)

Professional Cancer Care Experience Advisors, Beacon Advocates

- Providers are reluctant to order the tests because of all the steps they have to go through to get the approval.
- You are correct that it is important that the carriers update in real-time for the tests and that the carriers approve the tests for maintenance. Cancer is smart and can mutate. The new technology may be able to identify mutations that were not identifiable before.

Employer Action Steps

- Confirm with carriers that processes are in place to efficiently and proactively evaluate the 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 or 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.
- Recognize that some insurance plans will not cover the costs of biomarker tests and will deem them to be "experimental and investigational." This is more common in the insured plans than the self-insured. 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 are communicated without long delays.
  - Appropriate clinical experts are involved in appeals 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.

- 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 governing prior authorizations include specifics about any requirements around genetic; and biomarker testing for diagnosis, treatment, and/or post-treatment monitoring.
- 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 the 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
- Cancer Care – Employers' Prescription for Employee Protection Toolkit: Best Practices for Biomarker Testing Coverage

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

- Computer (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.
- Employers should inquire as to what is and is not being covered when it comes to AI.

Two Examples of AI Programs

1. SmartLinQ – When an oncology practice participates in the 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 the 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.
- These programs are not used and are not as user-friendly as they should be.

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 members and treating physician
- Have flexible pricing strategies, PMPM, or per-case administrative costs
- Other recommended criteria based on your experiences?

Comments

Miami-Dade County Public Schools

- Yes, we cover second opinions with PAs.
- We have two large health systems with cancer centers that rely on physicians having team discussions and multiple protocols in addition to AI.
- Miami Cancer Institute and the Sylvester Comprehensive Cancer Center call these team discussions physician huddles, and they meet first thing in the morning. A report on individual cases is delivered to the case manager at Cigna and Cigna reports each case, deidentified, to us. They will also bring in other specialists, if necessary.

Sargento

- You really need to remind everyone that they are out there. It is critical and helpful to make sure you have all of the information embedded in as many other resources as possible. Then, regardless of where they bump into a resource, they will be reminded and encouraged to use the service.
- We have had two people who were diagnosed with cancer, end up not having it so having the right diagnosis is imperative.

United Airlines

- We have a center-of-excellence program and we have found it helps give an employee reassurance that what they are having done, is correct. Secondly, it saves the plan money. This is a rare win-win.
- Physicians are happy to get a consultation from City of Hope, Northwestern, or Mayo Clinic.

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. This is a rapidly advancing technology but still very risky for the patient. A good resource for questions the patient should ask is the American Cancer Society – Questions Patients Should Ask so we're putting that in the guide as a strong resource. Stem Cell Transplants have been done for years but there have been a lot of advancements recently.
- Immunotherapy: The use of biologics (made from living organisms) to improve the immune system's ability to fight cancer cells. Six 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
- We put definitions of each of the above in the glossary of the guide.

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. Delays in treatment are the biggest frustration for a cancer patient.

- 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 the 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. These are the million-dollar drugs.
- MBGH has an Employer Action Brief: How to Pay for Cell and Gene Therapies.

Paying for Cell and Gene Therapies

- The cost per dose of course of Hemgenix is $3.5M, for Skysona is $3.0M, and Zynteglo is $2.8M.
- There are more in the pipeline.

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 the 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

- 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.
- We would love to move to a pilot stage, we just don't know now what the barriers will be or how other intermediaries are going to react. We do know there are many organizations looking at this thoughtfully and we want to see if there is an opportunity to collaborate to do something.
- Employers are already at risk for a whole new magnitude of benefit expenses. Not acting now could lead to the demise of employer-sponsored healthcare benefits as we know them.
- The Florida Alliance is inviting employers to their webinar on cell and gene therapies. They will talk about a reinsurance model and will have a representative from the Jacksonville Police Officers and Firefighters Health Insurance Trust which decided to cover Cell and Gene Therapies. The program is on Tuesday, November 21, 2023, 10 – 11 AM CT – 11 – 12 PM ET.

Question: What have you heard about manufacturers selling insurance for their drugs?

- I have heard some of this is going on. I have also heard some of them are going into outcomes-based contracts with employers so the employer pays according to the outcome achieved. There will be more and more of this going on. Manufacturers will be asking employers to take a risk and buy some insurance, and then they will receive the drug at a reasonable cost or free, depending on the arrangement.
- If we don't act on these drugs as employers, the federal government will.
- We all know of PCORI, and we all pay PCORI fees. This is a way to fund research programs. The same thing could be done to fund high-cost drugs.

Question: Are all of these covered by Medicare and Medicaid?

- There is limited coverage by Medicare and Medicaid. There are a lot of criteria to be met so it is hard to get it covered.
- A lot of these therapies are curative. (Cheryl)

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 are 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, 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 share 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.
- Accumulator Programs – PAPs provide a capped dollar amount per patient that is not applied to a patient's deductible/OOP Max. Once PAP is exhausted, the patient becomes responsible for the total payment until the 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 AFP assistance.

Polling Result – Question: Does your plan include a copay accumulator program?

- Yes – 57% (4/7)
- No – 29% (2/7)
- Don't Know – 14% (1/7)

Polling Result – Question: If yes, has your claims administrator contacted you concerning September 2023 legislation that limits which drug claims your accumulator can be applied to?

- Yes – 0% (0/5)
- No – 40% (2/5)
- Don't Know – 60% (3/5)

Polling Result - Question: Does the plan include a copay maximizer program?

- Yes – 11% (1/9)
- No – 67% (6/9)
- Don't Know – 22% (2/9)

Polling Result – Question: If yes, do you believe the copay maximizer program has helped members adhere to treatment in the long run after PAP assistance is exhausted?

- Yes – 50% (2/4)
- No – 0% (0/4)
- Don't Know – 50% (2/4)

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.
- On 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.

- Carriers are not acting on this. I feel they are waiting to see if there is an appeal.
- It is important for you to talk to your carrier to find out what they are doing about the September 29, 2023 decision and what it means to your plan. Do this to make sure you are not going to be in violation of a decision that was effective on the date of enactment.

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 in accessing 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, the use of funds involving employee premiums to pay AFP administrative expenses may constitute a 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 Funding 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 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?

Comment: You do not need to share now. You can reach out to me or Karen later. What we are hearing is that some are using them for reasons that surprised us and some cannot stop using them for reasons which are surprising. It appears that the large employers are not using them. (Cheryl)

Comment

Miami-Dade County Public Schools

- Uses copay maximizers and it has increased prescription adherence.

Supporting Clinical Trials

- The National Cancer Institute (NIH) provides help to interested participants and providers in locating clinical trials and what it takes to get into them.
- While ACA requires coverage of routine costs associated with participation in clinical trials, there may be differences between carriers regarding routine costs. For example, you are not required to cover any drug used in the trial, only drugs used to take care of the side effects.
- 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, but it gives the patient access to these non-FDA approved treatments.
- 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.
- 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. These employers want to be able to consider covering through an appeal process.
- 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!

Employer Insight & Guide to Oncology Management

- The culmination of all of this project's activities
- December 8, 2023; 2:30 – 4:00 PM CT, 3:30 – 5:00 PM ET
- 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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Summary of Questions to Ask Medical Carriers and Employer Actions

Questions to Ask Your Medical Carriers

Biomarker Testing

- Does the plan include coverage for expert guideline-recommended cancer biomarker testing (NCCN, ASCO, CAP)? If yes, is prior authorization required for coverage?
- Is the plan real-time updated as new guidelines and FDA-approved biomarker tests are available?

- Does the 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 the plan waive the out-of-network financial penalty to the member?
- Does the plan cover biomarker tests for diagnosis, treatment, and ongoing monitoring?
- What are the rates of approved prior authorizations for testing and approved appeals when biomarker testing has initially been denied?

Artificial Intelligence AI

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

Cell and Gene Therapies

- 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 are initially denied?

Copay Accumulators, Maximizers, and Alternative Funding Programs, AFPs

- Does your plan include a copay accumulator program?
- If yes, has your claims administrator contacted you concerning September 2023 legislation that limits which drug claims your accumulator can be applied to?
- Does the plan include a copay maximizer program?

Clinical Trials

- 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?

Employer Action Steps

Biomarker Testing

- Confirm with carriers that processes are in place to efficiently and proactively evaluate the use of biomarker testing for diagnosis, treatment, and ongoing monitoring.
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- Recognize that some insurance plans will not cover the costs of biomarker tests and will deem them to be "experimental and investigational." This is more common in the insured plans than the self-insured. Confirm that:
  - Your plan has a strategy in place to ensure easily followed directions for appeal filing.
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- 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.
- 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 governing prior authorizations include specifics about any requirements around genetic; and biomarker testing for diagnosis, treatment, and/or post-treatment monitoring.
- 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 the use of broad-based plan coverage language: "Genetic/Biomarker Testing for diagnosis treatment and/or post-treatment monitoring, as approved by the Plan."
- Hold your carriers accountable. Know how many tests they are doing, denying, or denying multiple times and then approving. Pay attention to the reporting.
- The recommendation is to eliminate prior authorization. The oncologists who are ordering these tests know what they are doing and would not order if they are not necessary.

Artificial Intelligence, AI

- Know what is and is not covered when it comes to AI.

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
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- Remind everyone that they are out there. It is critical and helpful to make sure you have all of the information embedded in as many other resources as possible. Then, regardless of where they bump into a resource, they will be reminded and encouraged to use the service.

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- 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. Delays in treatment are the biggest frustration for a cancer patient.

Copay Accumulators, Maximizers, and Alternative Funding Programs, AFPs

- If your plan has copay accumulators, it is important for you to talk to your carrier to find out what they are doing about the September 29, 2023 decision and what it means to your plan. Do this to make sure you are not going to be in violation of a decision that was effective on the date of enactment.

- Carefully evaluate associations with AFPs as issues concerning ERISA and IRS compliance are coming into play. For example, as outlined by VIVIO, the use of funds involving employee premiums to pay AFP administrative expenses may constitute a 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.
- Check out the MBGH Employer Action Brief: Copay Accumulators, Copay Maximizers, and Alternate Funding Programs: Friends or Foes?
- Involve legal, employee relations, employee, and risk reduction representatives in the decision-making process.
- Ensure cost savings analyses include disclosed administrative fees 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.

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. These employers want to be able to consider covering through an appeal process.
- 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.
- Save the Date – Final event December 8!