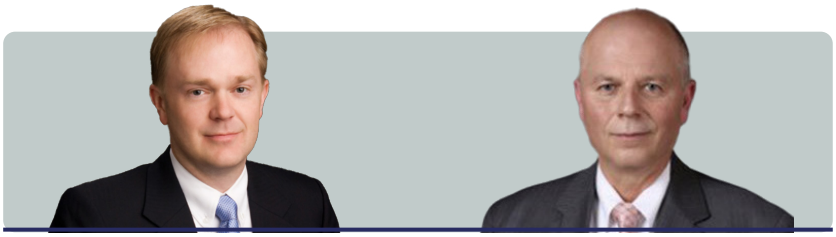
GHAPP National Workshop: Breaking Payer Barriers



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In this session, Drs Pezalla and Dunn used case studies and interactive discussion to explore the dynamics between payers and providers and to offer suggestions for improving patient access. The session began with a discussion of the current coverage status of glucagon-1 receptor agonists (GLP-1RAs), which are increasingly demonstrating benefits (eg, improved cardiovascular outcomes, renal outcomes, and sleep apnea) beyond their initial approved indications of diabetes and weight loss. Despite the overwhelming efficacy of these agents for weight loss and their growing list of indications, many patients lack access to these therapies because their employers have excluded coverage for weight loss drugs. This highlights the disconnect between short-term and long-term perspectives, whereby payers deny preventive therapies since patients may leave the plan within a few years, long before the cost to manage long-term complications arises.

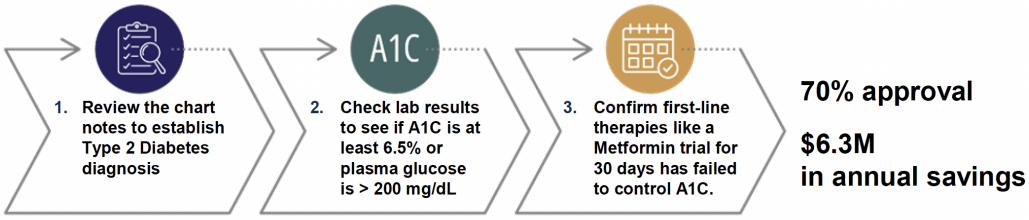
This lack of societal view in health coverage extends to many pharmaceutical products, including biologic and gene therapies, but has fortunately not penetrated all healthcare interventions. For example, most health plans cover vaccinations that are recommended by the Advisory Committee on Immunization Practices (ACIP) because they recognize that the benefits of establishing herd immunity extend beyond individual patients to the societal level.

Weight loss medication management strategies

Balanced approach. Prior authorization. Step therapy.

- **Thoughtful & Intentional Access:** Supports appropriate use of high-cost GLP-1s aligned with meaningful health outcomes
- **Balanced Utilization Strategy:** Ensure clinical appropriateness while managing cost and aligning with real-world utilization trends.
- **Whole Health Integration:** Partner-driven model includes behavior change programs and physician-supervised lifestyle plans to sustain outcomes.

Review Each Request to Evaluate the Full Clinical Context



70% approval

$6.3M in annual savings

Differentiating pharmacy benefits from medical benefits

Drs Pezalla and Dunn used the example of Linzess® (linaclotide) to illustrate how the prior authorization (PA) process works for typical pharmaceutical in GI medicine. As a drug that is self-administered by a patient or caregiver, Linzess will be covered under pharmacy benefits and listed on a formulary, which will specify a tier for the treatment. Specialty categories, which typically start around $800 per month, require PA. The PA process for Linzess is fairly straightforward and based on the approved prescribing information, with no step therapy requirements due to the lack of alternatives for the product.

Drugs administered by a healthcare provider are covered under medical benefits rather than pharmacy benefits. The health plan is responsible for decisions regarding payment and coverage for medical benefits. Drugs covered under medical benefits are not tiered and are subjects to caps from commercial plans, although these vary considerably. Drs Pazella and Dunn noted the need for better alignment between pharmacy and medical benefits, as inconsistencies in their structures can lead to therapies being preferred on the basis of financial exposure rather than clinical appropriateness.

Importantly, health plans can cover off-label indications for certain therapies, usually those supported by evidence-based guidelines. For example, the National Comprehensive Cancer Network (NCCN) guidelines are used to support coverage of off-label uses of oncology products.

Pharmacy benefits

- Drugs self-administered by patient or caregiver
- Source via a pharmacy
- Drugs are listed on a formulary
- PBM is responsible for payment/ coverage and decision making
- Medicare=Part D

Medical benefits

- Drugs administered by a healthcare provider
- Based on label and clinical trial
- IV, IM, and other forms
- Health plan is responsible for payment/ coverage and decision making
- Medicare=Part B

Linzess® case study

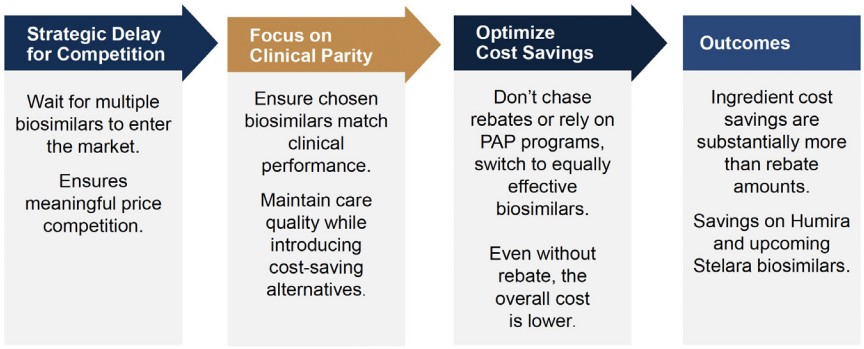
Oral drug	Pharmacy benefit
Tier	Preferred brand (copay $30-$50)
PA	For FDA-approved indications
Step therapy	None

Infliximab case study

IV drug	Medical benefit
Tier	No tiering in medical, co-insurance 20%
PA	For FDA-approved indications, renewal based on improvement Requires GI prescribing or consultation
Step therapy	May use only preferred biosimilars (Avsola, Inflectra, Renflexis)
Site of care	Sitie of care policy applies; must be administered in lowest cost appropriate site of care

Biosimilar strategy.

Lower costs. Less cash outlay. No waiting on rebates.



Annual Savings for Client X: $1,160,910 on Humira claims

Biosimilars represent a unique opportunity to reduce cost without sacrificing any quality of care. Further, given that autoimmune therapies are collectively the largest spend category of drugs globally, biosimilars have the potential to reshape drug affordability. Despite initial resistance from providers, their use is increasingly accepted has become more widespread in clinical practice. However, manufacturer rebate structures can incentivize employers or PBMs to prioritize rebate checks over net savings, ultimately discouraging switching to biosimilars. These types of rebates illustrate how misaligned incentives and lack of transparency distort true cost and can become a barrier to saving costs.

Despite the frustration and administrative burden caused by PA, this process is necessary due to the escalating prices of medical therapies in the United States. The PA process, which often includes the concept of stepped therapies, are a means of helping to ensure that cost-effective care is delivered. Although stepped-care policies can be cost-effective if the required first treatment is effective for the patients, they can also be inefficient and delay patients from receiving optimal treatment.

Recognizing that the most common reason for PA denials is missing information, Drs Pezalla and Dunn encourage providers to establish direct contacts with payers to determine exactly what data are needed for approvals. Since the information regarding PAs is publicly available, having staff consolidate the required information for approval of common therapies can improve efficiencies in the submission process. Notably, once payers are comfortable with a provider's prescribing practices and feel confident that therapies are being used appropriately, it is possible for PA requirements to be eliminated for that provider. This process, called Gold Carding, illustrates how building a relationship between providers and payers can improve the process. Drs Pezalla and Dunn emphasized that like providers, payers want to avoid denials and resubmissions as much as possible, hopefully eliminating frustration for all of the stakeholders in the long term.

> We understand how frustrating it is, but if we don't put a PA on a million-dollar drug, we're going to have all kinds of challenges. There's a finite amount of dollars in the system and we're trying to manage that as best as we can on a population basis.

> It's super-important for a provider to establish a contact at the payer organization. Once we are comfortable with prescribing practices and that medications are being used appropriately, then for certain practices and providers we eliminate the PA.