elixir
CRAFTED Rx SOLUTIONS

Four Strategies

To Successfully Manage Specialty Medications

While specialty medications provide a new level of hope for people being treated for serious conditions such as multiple sclerosis, hepatitis C and cancer, the costs of these medications can be very high. In fact, only about 1% of members use specialty medications, but they contribute to nearly half of overall drug spend.[1] With new specialty medications entering the market every year, these costs can impact members and plan sponsors alike.

The following four strategies provide a comprehensive approach to mitigate the financial impact of specialty medications while ensuring members receive the most benefit from their treatment.

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1 Review the Pipeline and New Drugs

In 2022, the FDA approved 37 novel drugs.[2] The Elixir team monitors this pipeline—including the more costly specialty medications—so they can be managed properly.

Monitoring Even Before FDA Approval

An important part of managing specialty spend is knowing what's on the horizon and understanding how various pipeline nuances (such as biosimilars and authorized generics) can impact drug spend downstream if not managed appropriately. At Elixir, our team of clinical pharmacists monitors and reviews drugs prior to FDA approval, including those receiving a new indication, tracking numerous pharmaceutical agents throughout the research and development process. Take for example a fictional drug we will call LxR-CUR. Our Clinical team began monitoring LxR-CUR early on during the research and development phase, following the clinical trials to gain an understanding of clinical efficacy and its potential place in therapy.

The New Drug on the Block

So what happens after a drug is approved? At Elixir, a report of newly launched drugs is generated and reviewed by our clinical pharmacists weekly. In this report, we see that our fictional drug LxR-CUR has launched! Like many newly launched drugs—both specialty and non-specialty—LxR-CUR is now going to go through our New-to-Market Block process. As the name implies, this process blocks prescriptions for new medications from processing through the pharmacy benefit until our Clinical team has had sufficient time to review and analyze all of the data associated with it. This includes clinical trial data and published consensus guidelines.

The steps involved in this review are critical to fully understand a drug's place in therapy, as well as proper formulary placement and utilization management strategies to ensure the most appropriate and cost-effective use of LxR-CUR for members.

This proactive preparedness also protects our clients from unnecessary spend. Think of the waste that would be involved if a drug was allowed to process through the system immediately after it launched, only to discover weeks later that the drug should have had strict prior authorization criteria applied. An even worse scenario would be if it was determined that there is insufficient evidence to support coverage at all! A recent example of this is with the Alzheimer's drug Aduhelm, which was approved via the FDA's accelerated approval pathway. The New-to-Market Block process allowed for adequate time to analyze all the data and ultimately determine to exclude this drug from the pharmacy benefit due to insufficient evidence. These decisions help mitigate risk for our clients, reduce excess spend and ensure appropriate use of medications to protect clients and members alike.

The Path to Formulary Placement

Let's take a closer look at this New-to-Market Block process and the individual steps involved as it pertains to our fictional drug LxR-CUR.

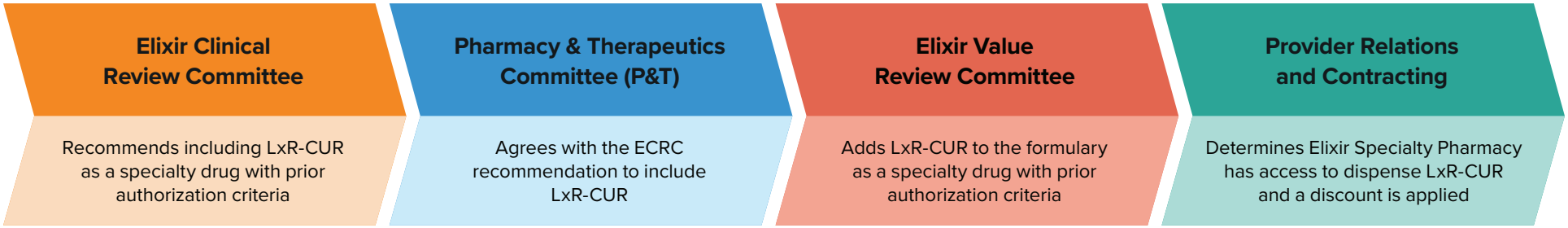
Elixir Clinical Review Committee (ECRC)
Elixir's Drug Information Pharmacists, who have been following the development of LxR-CUR, present all the clinical trial data, information from evidence-based literature, and safety and efficacy profiles to this internal committee comprised of clinical pharmacists from various teams throughout Elixir. The committee reviews the information and votes whether to include the drug, exclude (such as when there is insufficient evidence) or make formulary coverage optional. Initial utilization management strategies are also discussed.

Pharmacy & Therapeutics Committee (P&T)
Next up, P&T. The P&T Committee, comprised of external clinicians representing a variety of specialties and select ECRC members, has a mission of ensuring access to clinically appropriate, safe and cost-effective drug therapies. The committee reviews recommendations provided by the ECRC and applies their clinical expertise to provide their recommendation regarding LxR-CUR.

Elixir Value Review Committee (EVRC)
It is then the task of the EVRC to assess economic impact and the member experience to solidify LxR-CUR's place in therapy. This internal committee, comprised of employees from throughout the organization, analyzes the competitive market and uses the P&T Committee's decision to determine formulary placement.

Provider Relations & Contracting
Now that LxR-CUR has been determined to be included as a specialty drug under the prescription benefit, the Provider Relations & Contracting team, comprised of pharmacy network specialists, assesses the drug's availability in the market, with competitive discount offerings for limited distribution products. They develop performance criteria for strategic network participation and secure specialty pharmacy procurement through agreements and contracting.

With so many new medications coming to market, particularly pricey specialty medications, it is important to thoroughly assess new drugs with a thoughtful approach. Elixir's New-to-Market Block and comprehensive review process ensure newly approved drugs are properly evaluated to balance clinical effectiveness, economic impact and the member experience.



2 Implement Utilization Management Strategies

A proper utilization management strategy involves coverage criteria development for prior authorization.

The prior authorization (PA) process can be very effective in saving plans hundreds of thousands in wasteful spend, particularly with specialty drugs. In fact, the average savings per specialty claim denied for inappropriate use is over $6,000.[3] For a therapy filled once a month, that equates to just under $72,000 in savings a year—for one member!

While the term prior authorization infers "seeking permission" to take certain medications and some may think we're questioning the doctor, that is not the case. The PA process is a system of checks and balances that is critical for the specialty space due to the complexity of the drugs and the conditions they treat.

For this reason, PA is meant to ensure that it is the right drug, for the right member, at the right time and at the right dose. We know you've heard this before, so we're going to break down the significance of each of these principles and demonstrate how this utilization management strategy can assure we get it right, for both the member and the plan.

The Right Drug

Elixir clinical pharmacists develop coverage criteria for PAs based on documented evidence from practice guidelines,

clinical trials and other peer-reviewed medical literature. This evidence is used to determine if a medication is "the right drug." As part of that determination, we ask:

- Is the drug requested being used as experimental or investigational treatment for the diagnosis given?
- Is the medication being prescribed appropriately based on how it was studied?
- Is the medication for a high-touch disease state and being prescribed by the appropriate specialist?

These types of questions are built into the PA criteria to ensure the medication being prescribed is truly the right drug.

The Right Member

Determining the right member for a prescribed specialty drug is equally important—both from an efficacy and safety standpoint.

Certain drugs will only work in those with a specific genetic biomarker of a disease and lab work is needed to confirm this criteria is met. Some members stop responding to their biologic injectable specialty medications at a standard dose and the dosage is increased. In this case, Elixir requests the results of specific lab work to prove whether the higher dose is clinically appropriate or if they need to be switched to another drug. Some medications have been studied only in adults and would not be safe in the pediatric population. That is why additional questions are included as part of the PA process to verify the member is an appropriate candidate for the drug requested.

The Right Time

Not all new drugs to market are the first ever to treat a particular disease. Many drugs are similar to other products already on the market with established efficacy. For that reason, additional layers are added into PA criteria to account for appropriate trial and failure of more cost-effective, first-line treatment options, whether that be an alternate formulary branded product, a biosimilar or the FDA-approved generic equivalent. Ensuring proper timing of drug use ensures that the most cost-effective therapy is approved and clinically backed by established treatment guidelines and evidence-based medicine.

The Right Dose

For safety purposes, many drugs have specific dosing requirements, particularly complex specialty medications. For this reason, PAs are multi-faceted and can include:

- Quantity limits
- Maximum daily dose limits
- Maximum day supply limits
- Loading and maintenance dose limits

A loading dose is when a member is given a certain dosage when starting the medication, sometimes double the ongoing maintenance dosage. Additionally, some treatments should only be used for a finite period of time, perhaps three or six months, and require limits on the length of approval. These various dosage limits ensure the member is receiving the correct drug strength for the correct diagnosis, administered at the correct frequency.

The Right Strategy

By applying the right utilization management strategies to specialty medications, we ensure the right safety measures are in place for these complex medications, which leads to better clinical outcomes for our members and eliminates waste from costly medications being used inappropriately.

LxR-CUR Example

LxR-CUR is a fictional drug that was added to our formulary as a specialty drug with the following prior authorization criteria:

THE RIGHT **DRUG**

Specialist Prescriber

Due to the high-touch nature of the disease being treated, any requests for LxR-CUR should be under direct supervision of an appropriate specialist.

THE RIGHT **MEMBER**

- **Appropriate Age**
- **Supporting Lab Work**

Members prescribed LxR-CUR must be adults and lab work needs to verify the member is positive for a specific genetic marker before an approval can be considered.

THE RIGHT **TIME**

First-Line Therapy Trial and Failure

LxR-CUR is not the most cost-effective first-line treatment available for the condition. We need to verify trial and failure of the first-line therapy before LxR-CUR can be approved.

THE RIGHT **DOSE**

Appropriate Loading and Maintenance Doses

Since LxR-CUR has a higher starter, or loading, dose before a maintenance dose is given, our PA process requires a limit of two months for the higher starter dose, preventing claims for the higher dose to continue to process and eliminating wasteful spend.

3 Predict the Financial Impact

Now, let's review the importance of planning for the financial impact of a new specialty medication.

The strategies we've already employed with formulary placement and utilization management ensure that it's the right drug for the right member at the right time and dose; however, with these medications costing an average of $5,000 per claim, plan sponsors need to prepare for how this will impact their budget.[4] Emerging new therapies focus on addressing the needs of rare, orphan or even genetic-related conditions. With the population being extremely small and drug costs typically extremely high, these therapies can have a profound financial impact on a member and plan, hitting both the prescription and medical benefit. Budget impact modeling can help a plan prepare for these circumstances.

Preparing for Pipeline Updates

In order to properly prepare for new specialty medications, it's important to keep an eye on the development pipeline. As mentioned earlier, Elixir's team of clinical pharmacists monitors and reviews drugs prior to FDA approval, tracking numerous pharmaceutical agents throughout the research and development process. We share information on pipeline developments with our clients in our Weekly Drug Update emails, including notable drugs in the research phase, recent FDA approvals, and new generics and indications. This insight allows clients to begin preparing before a drug is approved.

Predicting the Impact

Elixir can provide our clients with an in-depth predictive view of a drug and its potential impact based on the membership details, whether it's a new specialty drug to market, a new or expanded indication for an existing medication, or a generic or biosimilar becoming available. The analysis considers the client type (i.e., Medicare, Medicaid or commercial) and size. With this data, we compare the new or updated drug to existing medications that are approved to treat the same condition, summarizing the potential cost impact over time, whether it be additional spend or savings.

With this insightful tool, we can provide clients with predictions on the following:

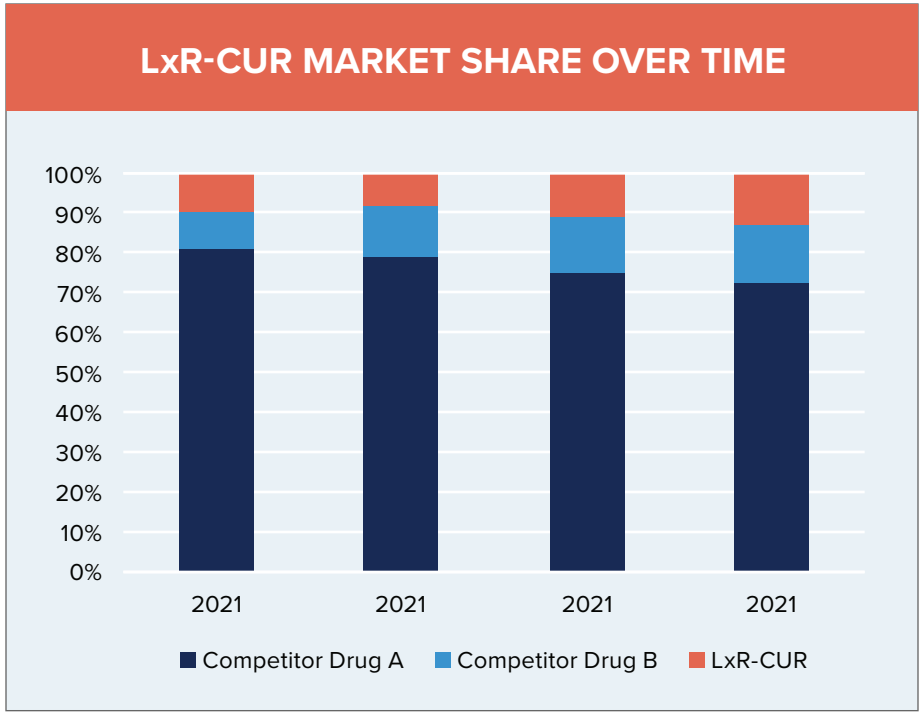
- Number of members who might utilize a particular drug
- Expected cost of a new drug
- Impact of a generic drug entering the market
- Per member per month (PMPM) costs
- Cost shifts when additional treatments are approved

In addition, we can share with clients what diagnosis codes to look for within medical claims to determine if a member has a rare condition that a new orphan drug treats in order to more accurately predict the financial impact of that therapy.

Let's take for example our fictional drug, LxR-CUR. This specialty medication was just approved in January of this year to treat an inflammatory condition that affects approximately 6 million adults, with around 70% of those diagnosed seeking treatment. For our analysis, we compared it with two different medications already on the market, Competitor Drug A, approved in March 2017, and Competitor Drug B, approved in September 2020. Both medications have demonstrated significant efficacy in treatment of the disease, with a 75%+ response rate and cost between $80K and $100K per utilizer per year (PUPY). While LxR-CUR was not studied head-to-head against these medications, it has demonstrated similar high efficacy and safety profiles at a cost of $95K PUPY. Following are the results of the analysis for a 20K-life commercial plan:

	2022	2023	2024	2025
Members Expected to Receive LxR-CUR Therapy	**5.1**	**5.8**	**6.8**	**8**
Annual Est. of Plan Costs for LxR-CUR Therapy				
Total Annual Estimate Plan Financial Impact	**$484,500**	**$552,330** (+14%)	**$646,226** (+17%)	**$0.82** (+17%)

	2022	2023	2024	2025
PMPM Impact of LxR-CUR Utilization	**$0.53**	**$0.60** (+14%)	**$0.70** (+17%)	**$0.82** (+17%)



Proactive Preparedness

While sometimes, there's only so much you can control when a member starts taking a pricey new specialty medication, particularly when there are no other options to treat a serious condition, Elixir's budget impacting tools allow our plans to proactively prepare for new therapies to market using data, trends and facts so it's not like receiving a sucker punch to the budget. This information can be empowering and ease anxieties, allowing plans to make informed decisions about plan design, budget accordingly and put measures in place to create cost efficiencies, all while ensuring the member has access to potentially life-saving medications.

4 Provide Individualized Care

The last step in managing specialty medications, plan sponsors must ensure that their members are getting individualized care from the specialty pharmacy in order to get the most benefit from these complex medications, minimize waste and alleviate additional costs from other healthcare complications.

The complexity of specialty medications can lead to several questions or hurdles that members taking these treatments need assistance with, including:

Proper Storage and Handling – Some medications need to be kept at certain temperatures or stored under specific conditions. There also might be protocols to follow when administering the drug.

Administration Technique – Many specialty medications are self injected. Members might require assistance on proper injection techniques or may benefit from tips to avoid injection fatigue, miss fires and medication wastage.

Complicated Dosing Schedules – With some specialty medications, complicated dosing schedules can cause confusion for members. For example, loading doses and adjuvant therapies may require different dosing strengths, quantities, frequencies and even dosage forms prior to converting to long-term maintenance treatment.

Side Effects – There are various side effects that individuals may experience while taking specialty medications, some that may be intolerable. Providing advice for managing side effects or starting treatment at an appropriate time can help individuals overcome side effect hurdles and remain on therapy.

Costs – Just as specialty medications are expensive for plan sponsors, they are costly for members too. Members often need financial assistance to afford their prescription.

Individual Response – Many of the conditions that specialty drugs treat manifest differently from person to person and each individual's response to treatment is different. Condition-focused controls ensure the right treatment plan for the member and continual monitoring is essential to ensure optimal outcomes from the therapy.

A High-Touch Care Model

Beyond simply dispensing the medication, Elixir Specialty provides an individualized care model that provides support to members before, during and throughout treatment to optimize outcomes.

Prior to Treatment – Elixir Specialty's certified specialty and often disease-certified pharmacists work directly with members before shipping the first dose of a specialty medication to ensure their readiness to start treatment and their overall

commitment to the regimen, determining where the member is in their treatment journey and identifying any potential barriers to care. We educate the member on what to expect from their treatment, potential side effects and drug interactions, and discuss any key points that can affect therapy.

For certain conditions, a pharmacy specialist performs a readiness screening to determine if the member would benefit from an alternate start date due to other illnesses or to lessen the impact from side effects on daily living. This helps improve adherence, which is crucial for most specialty medications.

For those receiving injectable treatment, we link them to a pharmacy staff specialist, available 24/7 for counseling and injection support. We develop customized care plans for the member, which are condition and drug focused, with the pharmacist spending 20-30 minutes or more with the member during this initial assessment.

At the Start of Care – We assess all members at the start of care to determine if copay assistance programs are available, either through the manufacturer, governmental programs or non-profit foundation organizations.

During Therapy – Members receive clinical support throughout the course of treatment. We empower the member's voice to gain insight into their treatment journey, discover opportunities to mitigate barriers and optimize care. We do this by using several different screening tools and questions. It's more than simply counseling or telling the member they can reach out to us at any time. It's gauging comfort with therapy. We do this by:

- **Screening for issues such as itch, affected body mass and depression**
- **Evaluating the member's confidence in their treatment**
- **Assessing for missed doses and side effects**
- **Customizing care plans to address issues**
- **Collecting lab results for appropriate disease states to track therapy effectiveness**
- **Intervening when needed to help members overcome barriers**

All of it is done with a commitment to helping the member achieve their therapy goals.

LxR-CUR Example

The following are steps Elixir Specialty would follow with members starting on LxR-CUR therapy:

PRIOR TO TREATMENT

- Review member's medical history, educate on condition and discuss treatment expectations
- Confirm with laboratory tests that condition can be treated with LxR-CUR
- Educate member on loading dose and maintenance doses
- Determine member failed on two previous first-line treatments and this is her first self-injection therapy
- Provide self-injection training

START OF TREATMENT

- Secure copay support from the manufacturer to ensure member can afford LxR-CUR
- Ship first dose

DURING THERAPY

- During a regular check-in, the member reports that injections are more painful on the right side of her body
- After discussions, the pharmacist determines that the problem was with the angle of the injection when she injected her non-dominant side due to limited dexterity and was causing site inflammation
- The pharmacist provides injection rotation and site selection education and recommends the member apply a topical antihistamine she has on hand
- Going forward, the member did not report any further issues and was able to remain on her treatment, receiving optimal outcomes

The Elixir Difference

Elixir Specialty's dedication to the member is the difference between simply supplying a medication and truly impacting the quality of a member's life. Knowing that every member's story is unique, we provide a proactive, hands-on pharmacy approach that is disease- and drug-specific, as well as tailored to each member's individual needs.

Our comprehensive strategy to manage specialty medications can help you limit waste of pricey drugs, improve clinical outcomes, and lower the total cost of care as we help members achieve whole health for life.

1. Seymore, Brandeis (2020). Challenges of Channel Management for Specialty: Medical Benefit or Pharmacy Benefit. Pharmacy Times. July 10, 2020. https://www.pharmacytimes.com/view/challenges-of-channel-management-for-specialty-medical-benefit-or-pharmacy-benefit.

2. U.S. Food & Drug Administration. Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022.

3. Elixir book of business

4. U.S. Pharmacist (2021). Net Spending on Specialty Pharmaceuticals Surging. https://www.uspharmacist.com/article/net-spending-on-specialty-pharmaceuticals-surging.

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