



Formularies: What Are They and How Do They Work?

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Davis Phinney Foundation

Leigh Cocanougher (Education Program Manager, Davis Phinney Foundation):

Hello everyone. I'm Leigh Cocanougher with the Davis Phinney Foundation and we're here today to talk about an incredibly important and timely topic for the Parkinson's community and wider community as well and that is the topic of formularies. We want to thank today's sponsor for this interview, Amneal, for helping us provide this educational content to our community for free and here today to help us dig into this topic is Derek Arnold. Derek is the Vice President for Market Access and Trade at Amneal Pharmaceuticals where he leads a team that helps ensure patients have access to Amneal's medications and that they are affordable. This includes helping ensure healthcare providers and physicians can prescribe Amneal's medications with minimal insurer pushback and rejections. His team also puts into place patient support programs to help make medications affordable, to help doctors get patients approved for therapies faster, and to support Amneal's Patient Assistance Program which offers free therapy for patients who meet the eligibility requirements. He has spent the last 30 years in pharmaceuticals, the most 25 of which have been in market access interacting with insurers and large hospital systems. He has three children and lives in Virginia with his wife and five Labradors. Derek, thank you so much for joining us today.

Derek Arnold (Vice President for Market Access and Trade, Amneal Pharmaceuticals):

It's great to be here Leigh. Thank you.

Leigh Cocanougher:

And one reason we're especially excited to have this conversation now in the beginning of November is because it's open enrollment season for Medicare part D. Medicare part D open enrollment this year began on October 15th and it ends on December 7th, 2021, so this is an excellent time to review the current plan you are on to determine if your medications, branded, generic, or both are covered. You should be mindful that benefits and premiums could change from one year to the next so even if you are confident that you want to keep your current coverage for the next year, it's important to make sure of any changes that apply going into 2022. If you need assistance in determining which Part D Plan cover one or more of the prescriptions you will be taking in 2022, you can log into [CMS.gov](https://www.cms.gov), click on the Medicare tab, and review coverage options. Alright let's jump in. Derek, first, what is a formulary and what do people with Parkinson's need to know about it?

Derek Arnold:

Sure great question. So, a drug formulary is a list of prescription drugs, both generic and brand name, that are preferred or covered by your health plan. Your health plan may only pay for medications that are on the list. Preferred drugs usually have lower copay or coinsurance than non-preferred drugs. In addition, a non-preferred drug may require the patient to try and fail other preferred drugs before the health plan will pay for the non-preferred drug. Health plans usually will only pay for medications for the specific indication that has been approved for sale by the U.S. Food and Drug Administration, the FDA.

Leigh Cocanougher:

And who creates the formularies and what do they involve?

Derek Arnold:

Well in most health plans, Leigh, the formulary is developed by a pharmacy and therapeutics committee composed of pharmacists and physicians from various medical specialties. The committee reviews new and existing medications and selects drugs to be included in the health plan's formulary based primarily on safety and how well they work. The committee then selects the most efficacious that includes a benefit risk profile and usually the most cost-effective drugs in each therapeutic class. A therapeutic class is a group of medications that treat a specific health condition or work in a certain way.

Leigh Cocanougher:

So what determines whether someone's insurance plan covers their medication?

Derek Arnold:

Well drug formularies are developed by the health plans and the pharmacy benefit managers based on efficacy which includes the benefit risk profile, safety, and cost of the drugs.

Leigh Cocanougher:

And how does being on a formulary impact what a patient may pay for a drug?

Derek Arnold:

That's a great question. So, a formulary has different tiers, and the health plan divides drugs into groups or tiers based mostly on cost. A health plan could have three, four, or five tiers. In general, the lowest-tier drugs are the lowest cost. Plans negotiate pricing with drug companies for their positioning. For example, Tier 1, usually would include generic drugs and a patient may pay \$4.00. Tier 2 could include preferred branded medications and the patient may pay for example, \$25. Tier 3 could include non-preferred branded medications and the patient may pay as much \$75 as an example. So, the higher the tier, the more cost out of pocket a patient may pay.

Leigh Cocanougher:



Okay. And as we talked a little bit in the beginning about open enrollment for Medicare Part D, what is the difference between a Medicare PDP and MAPD?

Derek Arnold:

Absolutely. The alphabet soup of Medicare, right? So, a “PDP” is the abbreviation used for a stand-alone Medicare Part D prescription drug plan. PDP, prescription drug plan. A PDP provides coverage for your out-patient prescription drugs that are found on a plan's formulary. Typically, PDP plans require patients share in the cost of the medication mostly through co-insurance or a percentage of the cost of that drug. For example, if a drug costs \$400 and your PDP plan requires the patient to pay 40%, then the patient pays \$160 and the health plan pays \$240.

An “MAPD” is the abbreviation for a “Medicare Advantage Prescription Drug Plan”. An MAPD provides coverage for your out-patient Medicare Part D prescription drugs and it also includes coverage for Part A or any hospitalization as well as Part B your physician visits. It may also include supplemental benefits like vision or dental care as examples. Typically, an MAPD plans will require patients to pay a flat co-pay rather than co-insurance for the cost of the medication. For example, a formulary drug may cost the patient a flat fee of \$100.

Leigh Cocanougher:

Okay. That’s super helpful. So what about exclusions? What are exclusions and what causes a drug to be put on an exclusion list?

Derek Arnold:

Sure. Really interesting. So a formulary exclusion list includes the drugs that an insurer, a health plan, or a PBM, pharmacy benefits manager does not cover. So, your health plan could exclude a drug from the formulary for several reasons and these may include, Perhaps the committee selected a drug in the same therapeutic class that they’ve determined is sufficiently effective and more cost-effective for treating your condition. Another reason may be that the drug is actually available over-the-counter. Perhaps the FDA has not approved the drug. There may also be the reason that the health plan has concerns about the safety or efficacy of the drug. Another reason could be that the drug is determined as medically unnecessary. For example, if the drug is used for cosmetic purposes only. Another reason could be that the cost of the drug does not offset the benefits gained, right, the risk benefit profile. Perhaps, the drug offers little or no additional benefit from what is currently available. And finally, it could be that an employer group has made a decision that they will not cover a particular drug due to cost, or even moral or religious beliefs.

Leigh Cocanougher:

Okay. Thank you. And so how can a person with Parkinson’s find out that a drug they take every day is about to be put on an exclusion list?



Derek Arnold:

Well, so updates to a commercial Exclusion List, they're made public, basically quarterly by most all of the major PBM's and they're posted on the PBM websites. Medicare plans actually can't make changes to their drug list during a calendar year unless a generic version of the brand drug has been introduced since the drug list was established. This change is only allowed once during a calendar year, actually in July. Now as a patient, you could receive a letter 90 days before the change from the insurer or from the PBM stating that the drug is being removed from the Formulary. The physician that prescribed the medication may also receive the same letter, so that they too are aware that the PD medication, for example, they prescribed for their patient is now excluded from the patients' plan formulary. Now, Commercial and Medicare patients, or their HCPs, are usually notified by the payers a few months in advance if a drug is going to be moved from covered to excluded, not paid for. Finding out about a drug being put on an exclusion list prior to public posting would really require inside information from either the PBM, Payer or Manufacturer.

Leigh Cocanougher:

So what actions can people take if their drug lands on an exclusion list?

Derek Arnold:

That's a super important question. So, you could speak with your insurer about making a formulary or medical exception and having them provide coverage for your drug. Most likely, your doctor will need to submit a supporting statement, detailing that your drug is medically necessary and that the listed alternatives would not have the desired effect or have already been tried and failed. Some plans will require that you agree to a "step therapy" before your exception gets approved. Now, step therapy is where you try a less expensive drug that's on the plan's formulary, thereby proving that it's not effective or has unacceptable adverse effects for you, then you're allowed to move up a "step" to the more expensive drug that you're requesting. Now, many states have laws in place to help ensure that once a patient has gone through a step process, that the patient can stay on a product that is beneficial for them without the need of going back through a step process. In the case of a commercial patient who is insured through their employer, it may also be helpful to reach out to your company health benefits manager to see if they can assist you in getting a product covered, particularly, if the medication allows you to continue employment.

Leigh Cocanougher:

Okay. Great, thank you Derek so much for sharing this invaluable information. And thank you again to Amneal for sponsoring this interview and helping us to spread this work about formularies and open enrollment to our community. Thank you so much everyone for joining us and we will see you again soon.



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