Considering Authorized Generics in Pharmacy Benefits Design

Lipitor® or Atorvastatin Calcium. Zoloft® or Sertraline Hydrochloride. The differences in their names are vast, yet they are therapeutically equivalent and FDA-approved (see list here).

Of all the generics on the market today, about 1,000 are classified as Authorized Generics (AG). An AG is a drug that is made by the same manufacturer as the brand-name counterpart. They are identical, having all the same characteristics and ingredients (active and inactive) and the same safety and effectiveness. They are made in the same manufacturing facility as the brand drug and held to the same quality standards.

Traditional generics do not have to follow the same high-quality standards required by the FDA. This is particularly important because over 80% of the ingredients that come from overseas generics receive less rigor and oversight than those manufactured in the US. Non-AG (generic) manufacturers are not required to meet any quality checks with some overseas manufacturing plants not inspected by the FDA.

The release of an AG comes on the heels of the brand drug coming off patent. This allows them to offer the drug under the same generic name as well.

This paper will examine this class of drugs, their impact on the marketplace and provide guidance to employers to help ensure AGs are covered under the pharmacy benefit.

To control spending, employers should discuss AG coverage with their Pharmacy Benefit Manager or Pharmacy Benefit Administrator (PBM or PBA).

The FTC reports that AGs can bring down similar retail generics by 4-8%. When offered without a retail generic there is a 7-14% savings compared to brand price.

This savings can be significant given the cost of some brand drugs. Employers should be encouraged by this data. As more AGs come to market, it is key that employers consider access to AGs for their members.

The Clinical Value of Authorized Generics to Members

Authorized Generics are the same in every aspect to their brand counterpart except for the drug name. Factors that contribute to an increase in adherence and decrease the switching back to the brand drug include:

- All of the testing, clinical trials, side effects and efficacy are a result of the years of experience from the brand name drug.
- Made in the same facilities as the brand name drug meeting FDA quality and manufacturing standards.

The pill form is the same shape, size and color as that of the brand name drug with the same strength and dosage.

Important elements to consider:

- Costs for AGs are lower than their brand name counterparts, which can increase adherence and lower the switching back to brand drugs.
- Plan members who are sensitive to inactive ingredients found in standard generics can cause a patient to switch to the higher-cost brand. AGs are the same as the brand.

In collaboration, the Mid-America Coalition on Healthcare (MACHC) and the Midwest Business Group on Health (MBGH) publish this report to bring cost management strategies to employers to help as they manage pharmacy benefits.

The sensitivity to inactive ingredients was highlighted in a 2018 British Medical Journal peer-reviewed article where more patients switched back to brand from traditional generics than those who moved to Authorized Generics and did not switch back.
Call to Action

Many employers are serious about driving down costs yet want to make sure their members have access to therapies that treat complex, chronic, life threatening and rare medical conditions.

Here are steps employers can take now to improve use of Authorized Generics:

**Action Steps for Employers**

1. Provide the [FDA's list of AGs](https://www.fda.gov) to your carrier or PBM/PBA to review your formulary and have a discussion on how to add them to your contract for adoption.
   - Where a brand is indicated or prescribed ensure the appropriate clinical protocols are in place to direct members to AGs similar to what is in place for retail generics.
   - Where there is a retail generic in place for a brand that also has an AG, ensure AG formulary access by members.
2. Be certain the contract defines any rebates received for AGs and that audit rights are in place.
3. Track utilization by drug class in medical and pharmacy data to determine where the greatest opportunity exists to leverage AGs.
4. Track data and utilization of AGs to compare to brand and generic utilization to report on savings and improved non-switching back to generics.
5. Ensure the correct benefit design is in place to drive utilization to AGs. (E.g. consider matching AGs to the same pricing tier as retail generics.)
6. Inform members of the availability of AGs via benefit and PBM/PBA communication channels.
7. Consider mandatory replacement for brand drugs where an AG is available.
8. If #7 is not possible or desired, consider a co-pay differential when a brand is chosen over an AG.
9. Examples of more aggressive strategies for AG consideration:
   - Consider a lower co-pay tier.
   - Attach performance guarantees or shared savings targets to your PBM/PBA.
10. Inform members about cash payment options that may be lower cost.
11. Future consideration: As new AGs come to market ensure your PBM/PBA is adding them to the formulary upon release. Given AGs are the exact same drug, there should be no clinical reason to withhold from the formulary.
12. Future Consideration: To save costs for the plan and member, consider direct contracting with a retail pharmacy to enable members to pay a low cash price for AGs.

Discuss access to AGs with your PBM/PBA to check availability of them at network pharmacies. Some may not keep them in stock. Your PBM/PBA may have a solution for this situation as you plan to make AGs available to members.

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**Product Name** | **Brand Drug** | **Authorized Generic** | **Generic**
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Diflucan 150mg (fluconazole 150mg) | ![Image](image1.png) | ![Image](image2.png) | ![Image](image3.png)
Actevella 1-0.5mg (Lopressor 1-0.5mg) (estradiol & norethindrone acetate) | ![Image](image4.png) | ![Image](image5.png) | ![Image](image6.png)
EpiPen (Epinephrine auto-injector) | ![Image](image7.png) | ![Image](image8.png) | N/A
Strattera 25mg (atomoxetine 25mg) | ![Image](image9.png) | ![Image](image10.png) | ![Image](image11.png)

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