



## 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.



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.

*"I had very limited knowledge of Authorized Generics until I started learning more about them from my coalition. This helped me have a good discussion with my PBM."*

*"Authorized Generics give me another tactic for my pharmacy benefit toolbox by offering a cost-effective solution to my members who have challenges taking generics."*

Product Name	Brand Drug	Authorized Generic	Generic
Diflucan 150mg (fluconazole 150mg)			
Activella 1-0.5mg (Lopreeza 1-0.5mg) (estradiol & norethindrone acetate)			
EpiPen (Epinephrine auto-injector)			N/A
Strattera 25mg (atomoxetine 25mg)			

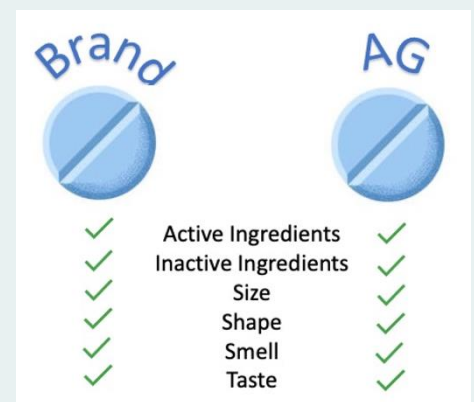
## Call to Action

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 [FDAs list of AGs](#) 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 insure 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.*