



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)			

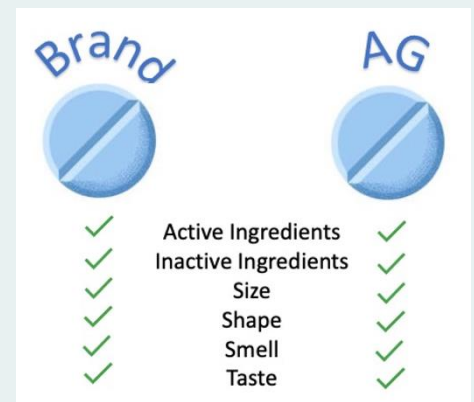
Call to Action

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.