Pharmacy Management Drug Policy

SUBJECT: Generic Advantage Program / MAC Penalty Determinations
POLICY NUMBER: PHARMACY-16
EFFECTIVE DATE: 08/2010
LAST REVIEW DATE: 07/10/2023

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☐ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☐ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Generic drugs have to meet the same rigid standards as brand name products. To gain FDA approval, a generic drug must:

- Meet the same batch requirements for identity, strength, purity, and quality
- Be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products
- Contain the same active ingredients as the innovator drug
- Be identical in strength, dosage form, and route of administration
- Have the same use indications
- Be bioequivalent

Pharmacy Management prescription drug benefits are designed to help our members save money by encouraging them to choose value when selecting prescription medications. The Generic Advantage Program for maximum allowable cost (MAC) promotes the use of generic medications.

Under this program, if a member fills a brand name medication when there is a generic equivalent available, the member will pay the generic co-payment/co-insurance amount, in addition to the difference between the cost of the more costly brand-name medication and our price for the less expensive generic. This is known as a MAC penalty.

Pharmacy Management Process Policy
Generic Advantage Program / MAC Penalty Determinations

POLICY:

Requests for MAC penalty exceptions will be reviewed based on the following clinical criteria (#1, #2 or #3). Please note that requests based on financial concerns only will not be authorized.

1. The member has had a documented **inadequate response** to a minimum of a 4 week trial of the **exact** generic equivalent drug
   - Must have tried maximum tolerated dosing (within FDA dosing limits) of the medication requested.
   - Will require documentation of exact dates that the generic was tried.
   - Will require patient progress notes documenting the outcome of the trial including either an subjective or objective description of the inadequate response
   - Will require pharmacy receipts/log documenting the trial of the generic if prior use is not confirmed in claims history. **OR**

2. The member has had a documented **allergic reaction** to an **excipient** that is present in the generic formulation but is absent in the brand name equivalent.
   - Will require documentation of exact dates that the generic was tried.
   - Will require patient progress notes documenting the allergic reaction that occurred.
   - Will require pharmacy receipts/log documenting the trial of the generic if prior use is not confirmed in claims history. **OR**

3. The member has experienced a **life-threatening side effect** that required medical intervention to a generic medication that did not occur with the brand.
   - Will require documentation of exact dates that the generic was tried.
   - Will require patient progress notes documenting the side effect and intervention required.
   - Will require pharmacy receipts/log documenting trial of generic if not confirmed in claims history.

POLICY GUIDELINES:

1. Authorization will not be granted if there is no documentation of the previous attempt of the generic (such as pharmacy log/receipt, progress notes, etc.).
2. A trial of an authorized generic will not be accepted as an exact generic trial. According to the U.S. Food and Drug Administration, an authorized generic is “an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product.”
3. The health plan will provide a MAC penalty exception on a brand name oral chemotherapy drug with an exact generic equivalent if the prescriber submits a request for a MAC penalty exception based on medical necessity. If approved, the drug will pay at the standard cost share for the benefit.
4. Generic Advantage Program may not apply to all benefits.
5. Select drugs may be excluded from the Generic Advantage Program for clinical, financial, or regulatory reasons
6. Standard approval time is 2 years. In addition, a MAC penalty exception will be backdated for a maximum of 1 month.
7. Approvals are based on medical necessity, not on financial hardship.
8. The member is not being denied access to the requested brand medication if the exception request is not authorized.

UPDATES:

Date:	Revision:
07/2023	Updated
05/2022	Updated
06/2021	Reviewed
07/2020	Reviewed
07/19	Reviewed
08/18	Reviewed
08/17	Reviewed
08/16	Reviewed
08/15	Reviewed
08/14	Revised
11/13	Reviewed
07/13	Revised
09/12	Reviewed
08/10	Created

REFERENCES:

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2. FDA list of authorized generic drugs. FDA. Published online March 31, 2022. Accessed May 11, 2022. https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs
3. Kesselheim et al. Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526
4. Davit et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97.