

**Pharmacy Medical Benefit Guidelines**

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<b>Approved By:</b>	Highmark Health Options – Market Leadership
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<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 2

**Disclaimer**

Highmark Health Options reimbursement policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

**POLICY STATEMENT**

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

**POLICY PURPOSE**

This policy was written with the intent to help bring an understanding and guidelines pertaining to FDA diagnosis and dosages of drugs in the medical benefit.

**DEFINITIONS**

**Highmark Health Options** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

**Off label Drug** – A use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information.

**Package Insert (PI)** – Drug prescribing information prepared by the drug manufacturer and approved by the Food and Drug Administration (FDA). The package insert includes details and directions that health care providers need to prescribe a drug properly, including approved uses for the drug, contraindications, potential adverse

reactions, available formulations and dosage, and how to administer the drug. The package insert is included with drug packaging and is used to develop any promotional or labeling materials.

### **POLICY POSITION**

Highmark Health Options utilizes pharmaceutical package inserts endorsed by the US Food and Drug Administration as a baseline for the medical benefit.

If claims are submitted with a non-medical FDA diagnosis, claims will deny.

Claims should be submitted with appropriate national drug code(NDC).

If a claim would deny, providers have the right to appeal/dispute. Once Appeal/dispute is reviewed, the provider is notified of the decision to either uphold the denial of payment or is overturned to pay the disputed code.

For any medications that are reported for an off label use, prior authorization is required.

### **References**

<https://clinicalinfo.hiv.gov/en/glossary/package-insert>

### **POLICY UPDATE HISTORY**

5.11.2023	Approved in Reimbursement Policy Committee
5.23.2023	Approved in Medical Policy Governance

