



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Formulary Non-Covered Drugs

Policy Number: 5.01.620

Last Review: 10/2018

Origination: 10/2016

Next Review: 10/2019

Policy

Various formulary decisions, described below, are considered not medically necessary.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Various formulary decisions, described below, are considered not medically necessary.

Considerations

Benefit design exclusions are not applicable to this policy and will continue to be defined by the individual policy, contract, or certificate. Examples, while not exhaustive, include non-FDA approved drugs; and New to Market drugs.

A BlueKC provider may request coverage at any time for a non-covered drug or New-to-market drug by utilizing the Prior Authorization Request process. Exceptions to this policy can be made when the patient has tried and failed at least 2 therapeutic formulary alternatives and sufficient clinical rationale has been provided to support FDA approved labeling.

Description of Procedure or Service

New-To-Market Drug Evaluation Process (NTM)

In an effort to make sure the new-to-market prescription drugs covered are safe, effective and affordable, coverage of many new drug products will be delayed until the plan's Medical and Pharmacy Management Committee (MPMC) has reviewed them. This review process is usually completed within six months after a drug becomes available.

Language in the member certificate exclude New to Market drugs as contract exclusion. Clinical exceptions may be requested within the first 6 months the drug is available, but until policy is determined, the new to market drugs may be excluded by contract.

Non-Covered Drugs may be identified by the following, not exhaustive:

- Drugs for which coverage is provided through an alternative claim category. For instance, drugs covered through the Medical benefit, drugs administered in facilities or through providers, including Home Infusion vendors, dialysis units, Oncology centers, outpatient settings, etc.
- New NDC code assigned to previously non-covered brand
- Benefit design exclusions
- Drugs determined to add no clinical value to existing formulary
- A new, different or modification to the existing drug delivery mechanism or system of a drug that is currently covered or not covered

- A different route of administration, formulation (salt, ester, or derivative or precursor) strength or concentration of an existing drug that is currently covered or not covered.
- Combination of an existing covered or not covered drug with an FDA or other agency clinically reviewed and approved prescription drug or product.
- Combination of an existing covered or not covered prescription drug with another drug or product that is excluded from coverage by benefit exclusion.
- Combination of an existing covered or not covered prescription drug with another drug or product that is not FDA or other similar agency clinically reviewed and approved for prescription.
- A new or different indication reviewed and approved by FDA or other agency for an existing drug that is currently covered or not covered.
- Line Extension of current non-formulary brand
- Exclusion based on question of efficacy or safety
- Exclusion based on planned medical/non-formulary status
- Exclusion or coverage modification based on approved future prior authorization or utilization management criteria
- The drug's marketing strategy may include couponing or sampling which influences a member or physician's prescribing from a more cost-effective, yet clinically effective therapeutic alternative
- Exclusion based on excessive high cost of drug, causing irresponsible fiduciary tactics

Rationale

To implement drug Formularies, a Prior Authorization program and Pharmaceutical Management programs at BCBSKC that are based on sound clinical evidence and which maximizes cost-effectiveness of available drug therapies, displays alignment with Medical and Pharmacy Management Committee (MPMC), Medical Policy, Account Agreements, and Subscriber Certificate guidelines.

It is the BCBSKC policy that any changes to the Formularies, Prior Authorization and Pharmaceutical Management programs will include an evidence-based analysis of clinical benefit with the goal maintaining our members' access to the pharmaceuticals prescribed by their physicians, consistent with the guidelines of the Medical and Pharmacy Management Committee (MPMC), Medical Policy, Blue Cross Blue Shield Association (BCBSA) Technology Assessment Committee (TEC), Account agreements and Subscriber certificates.

Billing Coding/Physician Documentation Information

NA Pharmacy and/or medical benefit drugs

Additional Policy Key Words

Policy number 5.01.620

Policy Implementation/Update Information

10/2016	New Policy titled Formulary Non-Covered Drugs
10/2017	Annual review-added clarifying language in an effort to contract exclude New to Market drugs
10/2018	No changes made

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