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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 12/12/2024

General Drug Utilization Management Policy

FDA Approved Drugs Unapproved Drugs Not Otherwise Classified (NOC) Drugs

HCPCS: N/A

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Drug is used in accordance with the FDA approved prescribing information.
 - b. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents.
 - c. For Part D drugs:
 - i. All medically accepted indications not otherwise excluded from Part D
 - ii. Subject to part B vs part D review
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Align with FDA recommended dosing
 - Quantity limits may align with recommended maintenance dosing. Use of maximum recommended doses may require review to assess appropriateness (for example, member has been adherent to a lower recommended dose and the dose is deemed ineffective)
 - b. Authorization Period: For at least 60 days and up to one year at a time
 - i. For Oncology Vendor Managed Medications Managed via General UM (i.e., supportive care and non-chemotherapy agents): Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time.
 - c. Renewal criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Bachground Information:

- The purpose of this policy is to provide:
 - Allow management of any drug according to the prescribing information.
 - Immediate criteria for new FDA approved drugs. This policy will represent drugs which are pending a full or abbreviated drug review for the P&T Committee.
 - Immediate criteria for existing drugs which have received a new FDA approved indication for which the medical policy has yet not been updated with this most recent indication. The new FDA approved indication will be represented by this policy until it is reviewed by the P&T Committee.
 - Immediate criteria for all drugs where we will follow up with development of a full drug/class specific policy if the criteria are more restrictive than the prescribing information.
 - When available, the applicable complete drug review with full criteria or policy will take precedence over this
 policy.
 - Allows Medicare Part D to apply general management as listed according to CMS guidance.

Policy History		
#	Date	Change Description
1.8	Effective Date: 12/12/2024	Updated to add alternative authorization period for drugs managed to label under General UM Policy by oncology vendor.
1.7	Effective Date: 06/06/2024	Updated policy to remove criteria related to investigational drugs and updated authorization period to align with PA60.
1.6	Effective Date: 06/08/2023	Updated policy to apply to unapproved drugs
1.5	Effective Date: 12/09/2021	Updated authorization period language
1.4	Effective Date: 6/11/2020	Updated policy to allow management of drugs according to prescribing information
1.3	Effective Date: 4/16/2020	Updated title to reflect policy covered newly approved drugs and NOC coded drugs and added criteria stating the plan has the right to deem a new medication investigational
1.2	Effective Date: 02/06/2020	Annual Review
1.1	Effective Date: 2/14/2019	Updated language in criteria A.b. and added bullet 3 in background information to include coverage of trial of all preferred drugs for any drug until a full policy is developed
1.0	Effective Date: 08/09/2018	New Document

^{*} The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.