New Drugs to Market (NDTM)
Corporate Medical Policy

File Name:  New Drugs to Market (NDTM)
File Code:  5.01.VT204
Origination:  10/2021
Last Review:  New Policy
Next Review:  10/2022
Effective Date:  11/01/2021

Description/Summary

This Policy provides assistance in interpreting Blue Cross Blue Shield of Vermont’s Prescription and Medical Benefit plan for deciding drug coverage for new drugs to market (NDTM).

Definition:

Prescription Drugs and Biologics: products that are:
- Prescribed to treat, prevent or diagnose a medical condition;
- FDA-approved (or not FDA-approved if the use meets the definition of Medical Necessity and is not considered Investigational); and
- Approved by us for reimbursement for the specific medical condition being treated or diagnosed, or as otherwise required by law.

Policy

NDTM drug lists are generated monthly. NDTM coding occurs via the Adaptive Maintenance process or off cycle as necessary. Drugs could remain on the NDTM list for up to 6 months.

When a service is considered investigational

Prescription drug and biologics that are newly approved by the FDA are considered investigational until a thorough clinical review can occur by our Pharmacy and Therapeutics (P&T) Committee.
Rationale/Scientific Background

P&T is the appropriate venue for clinical discussion regarding merits of a drug. Typically, safety, efficacy, place in therapy are determined and appropriate clinical criteria to manage the drug are reviewed and approved. NDTM is a way to ensure that robust process is complete.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval may be required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.
If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2021</td>
<td>New Policy</td>
</tr>
</tbody>
</table>

Health Care Procedure Coding System (HCPCS) codes related to chemotherapy drugs, drugs administered other than oral method, and enteral/parenteral formulas may be subject to National Drug Code (NDC) processing and pricing. The use of NDC on medical claims helps facilitate more accurate payment and better management of drug costs based on what was dispensed and may be required for payment. For more information on BCBSVT requirements for billing of NDC please refer to the provider portal [http://www.bcbsvt.com/provider-home](http://www.bcbsvt.com/provider-home) latest news and communications.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors  Date Approved

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP
Senior Medical Director