BlueCross BlueShield of North Carolina

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Corporate Medical Policy

New-To-Market Specialty Drug PPA Requirements

File Name:	new_to_market_specialty_drug_ppa_requirements
Origination:	6/2017
Last Review:	9/2019
Next Review:	12/2019

Description of Procedure or Service

This policy addresses new-to-market specialty drugs and new labelled indications for specialty drugs, covered under the medical benefit.

Specialty drugs paid through the medical benefit are high-cost prescription medications used to treat complex or chronic conditions like cancer, autoimmune conditions or genetic disorders. Specialty drugs frequently require special handling (like refrigeration during shipping) and administration (such as injection or infusion). Patients prescribed specialty drugs must be monitored by medically trained staff to determine if the therapy is working. Patients must also be monitored for adverse emergent reactions with appropriate interventions.

Specialty drugs may be covered through either medical or prescription drug insurance. Specialty drugs that are available on the medical benefit typically require close provider supervision and are limited to certain provider settings (such as office, outpatient, ambulatory surgical center, or home health agency.

Specialty drugs are very expensive – $1,000 or more per month – and spending on them is growing 15 to 20 percent a year. And every year, the U.S Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) approves many new drugs. Starting in 2014, in order to expedite the development and review of these products, the FDA's CDER implemented a number of regulatory programs, including Fast Track, Breakthrough Therapy, Priority Review, and Accelerated Approval to speed up availability and bring new drugs to market in the US.

This policy addresses new-to-market specialty drugs that do not have a specific policy and new labelled indications for specialty drugs addressed in existing policies, covered under the medical benefit.

New-to-market specialty drugs are defined as drugs that have only been available for purchase on the US market for 90 days or less, from the FDA approval date. New-to-market specialty drugs are required to have prior plan authorization (PPA) but may not have a specific policy available for which criteria have been developed. Many new-to-market specialty drugs have limited published data and are often identified using an unlisted HCPCS code on claims submissions.

Related Policies:
Place of Service for Medical Infusions
Clinical Trial Services
Investigational (Experimental) Services
Medical Necessity

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Blue Cross Blue Shield North Carolina (Blue Cross NC) will provide coverage for new-to-market specialty drugs and new labelled indications for specialty drugs paid under the member's medical benefit, when the criteria outlined in this policy are met.

This policy is limited to new-to-market specialty drugs and new labelled indications for specialty drugs that are not addressed in a specific medical policy.

Authorizations will be limited to a 90 day approval. Re-authorization will be required after 90 days.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When New-To-Market Specialty Drugs are covered

New-to-market specialty drugs will be covered when no specific medical policy addressing the drug exists, **or**

A new indication for a specialty drug will be covered when the indication has been added to existing FDA labelling for a drug that is addressed in a specific medical policy but the new indication is not,

AND when the following criteria are met:

1) The requested use of the drug meets the FDA labelled indications for the applicable diagnosis or treatment; **OR**

2) The requested use of the drug is an accepted indication for treatment of cancer in one of the following standard reference compendia, for drugs approved by the FDA for treatment of cancer:

- The National Comprehensive Cancer Network Drugs & Biologics Compendium
- The Thomson Micromedex ® DRUGDEX ®
- The Elsevier Gold Standard's Clinical Pharmacology
- Any other authoritative compendia as recognized periodically by the United States
- Secretary of Health and Human Services.

Based on the standard benefit language for Blue Cross NC members, the plan will utilize the FDA's approved specialty drug guidelines as the criteria for coverage when a specific medical policy is not available.

Many specialty drugs covered under the member medical benefit have a specific policy available with written coverage criteria. **To determine if a specific medical policy is available please check the Blue Cross NC website:** https://www.bcbsnc.com/content/services/medical-policy/categorical-list.htm#Drugs

To review the Blue Cross NC prior plan authorization (PPA) list for an updated list of specialty drugs covered under the medical benefit, please use the following link: http://www.bcbsnc.com/assets/providers/public/pdfs/PPA-Service-Code-List.pdf

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

When New-To-Market Specialty Drugs are not covered

New-to-market specialty drugs are considered investigational:

1) When used for non-oncologic (cancer treatment) indications outside of FDA labeling;

2) When used for oncologic (cancer treatment) indications outside nationally recognized compendia recommendations with the highest level of evidence (i.e. Level 1, 2A, 2B).

Policy Guidelines

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Approval Date(s) and History, Letters, Labels and Reviews for FDA approved specialty drugs are located through the following link: https://www.accessdata.fda.gov/scripts/cder/daf/

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J3490, J3590, J9999, C9399

Scientific Background and Reference Sources

Senior Medical Director 6/2017

Drugs@FDA: FDA Approved Drug Products.
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

Medical Director review 9/2019

Policy Implementation/Update Information

6/30/17 New policy developed. Blue Cross Blue Shield North Carolina (BCBSNC) will provide coverage for new-to-market specialty drugs paid under the member's medical benefit, when the criteria outlined in this policy are met. This policy is limited to new-to-market specialty drugs that do not have a specific medical policy. Authorizations will be limited to a 90 day approval. Re-authorization will be required after 90 days. New-to-market specialty drugs without a specific medical policy will be covered when the following criteria are met: 1) The requested use of the drug meets the FDA labelled indications for

the applicable diagnosis or treatment; OR 2) The requested use of the drug is an accepted indication for treatment of cancer in one of the following standard reference compendia, for drugs approved by the FDA for treatment of cancer: The National Comprehensive Cancer Network Drugs & Biologics Compendium, The Thomson Micromedex ® DRUGDEX ®, The Elsevier Gold Standard's Clinical Pharmacology, Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services. Senior Medical Director review 6/2017. Policy noticed on 6/30/2017 for effective date 10/1/2017. (mot)

12/29/17 Policy reformatted to change from "medical" policy to "reimbursement" policy. No change to policy statement or criteria. (an)

12/14/18 Routine annual policy review. No change to policy statement or criteria. (an)

2/12/19 Policy type changed from "reimbursement" to "medical" policy. No change to policy statement or criteria. (an)

9/10/19 Updated policy to include coverage for new indications for a specialty drug when the indication has been added to existing FDA labelling for a drug that is addressed in a specific medical policy but the new indication is not. Medical Director review 9/2019. (krc)