Post FDA Approved Pharmaceutical Products, Medical Therapies, and Devices

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Version Number: 3	**Version Effective Date:** 9/1/2023
Policy Status: Active	**Next Review Date:** 9/01/2026

PROVIDER/ENTITY IMPACTED					
☒ PROFESSIONAL	☒ FACILITY	☒ DME	☐ AMBULATORY SURGERY	☐ LAB	☐ OTHER

LINES OF BUSINESS IMPACTED						
☒ COMMERCIAL	☒ BLUE MEDICARE ADVANTAGE	☒ ACA QHP[1]	☒ SMALL GROUP ACA	☒ JAA[2]	☒ FEP[3]	☐ DENTAL

[1] ACA QHP: Affordable Care Act Qualified Health Plan for Individual/Family [2] JAA: Joint Administrative Account [3] FEP: Federal Employee Program

Disclaimer

Blue KC has developed Provider Payment Policies to provide guidance on payment methodologies as they pertain to submitted claims. These policies are written following industry standard recommendations from sources such as:

- Current Procedural Terminology
- Centers for Medicare and Medicaid
- American Medical Association
- National Correct Coding Initiative
- Other professional organizations and societies

Coverage of any service is determined by date of service, a member's eligibility and benefit limits for the service or services rendered, all terms of the Provider Service Agreement, and other standards of coding rules and guidelines.

Final payment is subject to the application of claims adjudication and edits common to the industry.

For confirmation of which services may be eligible for coverage and description of when medical services are considered medically necessary, not medically necessary, or investigational, please contact:

- Blue KC Provider Hotline for Commercial lines of Business 816-395-3929
- Affordable Care Act Provider Hotline 866-859-3822
- Blue Medicare Advantage Provider Hotline 866-508-7140

In the event of a conflict between any policies, the Member's coverage document will govern.

Description/Application

Post-FDA-approved products, therapies, and devices are those that have already received Food and Drug Administration (FDA) approval to be marketed and sold and are now subject to ongoing post-market surveillance and studies (Phase IV trials). This post-approval phase involves monitoring for safety and effectiveness in real-world use, conducting additional research on new populations or conditions, and reporting any adverse events or issues to the FDA to ensure continued patient safety.

Policy

New pharmaceutical products, medical therapies, and devices shall be excluded from reimbursement for the first 6 months following FDA approval, (including new indications) unless the Pharmacy and Therapeutics Committee recommends a shorter exclusion period.

During this period, the Pharmacy and Therapeutics Committee analyzes current literature to determine, among other things, the benefits, and risks of each new FDA approved product, medical therapy, and devices under review.

Coding

N/A

References and Resources

Blue KC provider Reference Guide

Related Documents

N/A

Revision History

Version	Date	Summary of Revisions
001	9/1/2023	Initial version
002	9/1/2024	Annual review, there were no updates, or changes made to this policy
003	9/1/2025	Annual Review, there were no updates or changes made to this policy

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