# Interim Policy on New FDA Approvals

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Interim Policy on New FDA Approved Drugs policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies on newly FDA-approved drug products and/or indications that will require prior authorization. This policy will apply only until drug-specific criteria and/or indication-specific criteria can be developed, reviewed, and implemented. Once criteria are available, and the authorization provided from this policy expires, the subsequent prior authorization review, if applicable, will be completed using the drug-specific or indication-specific criteria that is available.

## POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Submission of medical records (e.g., chart notes, laboratory values, genetic testing, other tests or imagining, etc.) confirming diagnosis, documenting relevant history, and physician evaluation information.

Initial Criteria for Approval

A. The requested newly FDA-approved drug or the existing drug with a newly FDA-approved indication may be considered **medically necessary** when all the following criteria are met:
    1. The requested drug has NOT been excluded from coverage by Wellmark due to lack of demonstrated safety or efficacy, clinical benefit, or administrative program (i.e. exclusion at launch while awaiting P&T review, plan exclusions).
    2. There is no prior authorization criteria available for the new drug or for the drug's new indication to review the request.
    3. The diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information/package insert.
    4. The following additional requirements listed in the FDA labeling have been met:
        a. First line therapies have been tried and failed if applicable
        b. Any testing requirements have been met if applicable
        c. The requested use of the drug does not conflict with what is stated as a Limitations of Use if applicable
        d. Patient age requirement is met

5. The following additional requirements included in the clinical trial(s) have been met:
   a. Clinical trial inclusion criteria (e.g., genetic testing, comorbid conditions, prerequisite therapies) have been met
   b. Patient does NOT meet any of the exclusion criteria in the clinical trial(s)
6. The prescribed dosing will not exceed the maximum FDA approved dose.

**Approval** will be for **6 months** unless the FDA-approved treatment duration is less than 6 months.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

## REFERENCES


- U.S. Food and Drug Administration (FDA). Drugs@FDA: FDA-Approved Drugs. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.


## POLICY HISTORY

**Policy #:** 05.02.43
**Original Effective Date:** October 20, 2020
**Reviewed:** July 2022
**Revised:** July 2022
**Current Effective Date:** July 19, 2022