HIGHMARK WHOLECARE

Updated: 07/2026
PARP Approved: 07/09/2026

Prior Authorization Criteria

Non-Formulary Medication and Medications Requiring Medical Necessity Review

All requests for non-formulary medications and medications that require medical necessity review require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below. For requests for preferred and non-preferred medications, refer to the Pennsylvania PDL prior authorization guidelines. This policy applies to medications outside the scope of the Pennsylvania PDL.

For all requests for non-formulary medications and medications that require medical necessity review all of the following criteria must be met:

- The requested medication has a diagnosis that is one of the following:
  - an FDA-approved indication or
  - a medically accepted indication that is supported by nationally recognized compendia defined as one of the following:
    - American Hospital Formulary Service Drug Information (AHFS-DI): "supportive"
    - Drugdex (Micromedex): level of evidence Class I, Class IIa, or Class IIb
    - United States Pharmacopeia Drug Information (USP-DI)
  - Peer-reviewed medical literature:
    - Use supported by clinical research that appears in at least 2 Phase III clinical trials that definitively demonstrate safety and effectiveness
    - If no Phase III trial evidence is available, at least 2 Phase II clinical trials with reasonably large patient samples showing consistent results of safety and efficacy.
    - Phase II or Phase III trials must come from different centers and be published in national or international peer-reviewed journals.
    - Literature including scientific and medical publications. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).
- The medication is aligned with pertinent clinical treatment modalities based on current national treatment guidelines or peer reviewed literature.
- If an FDA-approved companion diagnostic test for the requested agent exists, documentation that the test was performed to confirm the diagnosis
- If a test with adequate ability is necessary to confirm a disease mutation exists, documentation that the test was performed to confirm the diagnosis
- The requested medication is being prescribed by or in consultation with an appropriate specialist (when applicable (i.e. a formulary product from the same class requires a specialist in its specific prior authorization criteria)).
- Documentation of all pertinent clinical information related to the request from available sources (i.e., Primary Care Physician, Facility Utilization Review Department, Medical Record Department) including but not limited to:
  - Age
  - Contraindications or intolerances member had to previous therapies
  - Treatment history
  - Past medications
  - Diagnosis/co-morbidities
  - Medical history

        - Current medications
        - Previous test results
        - Current laboratory results
        - Physical exam findings
        - Any other data or rationale to support the medical necessity of the request
    - The request cannot be for an experimental, cosmetic, or investigational treatment
    - The dose and frequency of the requested medication is appropriate based upon the FDA-approved package insert, nationally recognized compendia or peer-reviewed medical literature.
    - Formulary alternative(s) were adequately tried and failed. Documentation must be provided to support the following:
        - Whether or not the member was recently hospitalized and if so, whether or not the requested medication was initiated during this hospital stay. (While hospitalization will not guarantee approval of the medication, it will be factored in to the medical necessity review.)
        - Medication name(s) and dose(s)of the formulary alternative(s) tried
        - Dates of trial of the formulary alternative(s)
        - Documentation of reason for failure /discontinuation of formulary alternative(s)
            - If the discontinuation of formulary alternative(s) was due to side effect(s), documentation of the nature of the side effect(s)
            - If inadequate response to a formulary alternative(s) is noted, documentation that shows whether or not the dose was increased in an attempt to achieve a greater level of efficacy
        - If a BRAND/REFERENCE medication is requested and a GENERIC/BIOSIMILAR version of that medication is available, and both BRAND/REFERENCE and GENERIC/BIOSIMILAR are non-preferred or non-formulary, the GENERIC/BIOSIMILAR formulation will be authorized if the BRAND/REFERENCE medication is requested and all other applicable criteria is met
        - The member has tried the possible formulary alternatives for their diagnosis(es) OR reasonable rationale has been provided to indicate why other formulary alternatives cannot be tried.
    - The medication does not interact with other medications, which may result in a serious or life threatening adverse reaction.
    - The member does not have a contraindication to the requested medication
- **Initial Duration of Approval:** Up to 12 months dependent upon clinical discretion with consideration given to if the requested medication is classified as a maintenance drug.
- **Reauthorization criteria:**
    - Documentation from the provider the member had a positive clinical response and is able to tolerate therapy.
- **Reauthorization Duration of Approval:** Benefit is approved for the requested duration or up to 12 months dependent on clinical discretion.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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NON-FORMULARY MEDICATIONS AND MEDICATIONS REQUIRING MEDICAL NECESSITY REVIEW PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

☐**FOR ONCOLOGY USE**

Diagnosis:_____ ICD-10 Code:_____

Is the member currently or recently hospitalized? ☐ Yes, date of discharge:_____ ☐ No

You must be able to document the therapeutic failure or contraindication to formulary products for a request to be approved.

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date