

Prior Authorization Criteria

Non-Formulary Medication/Medical Necessity

All requests for Non-Formulary Medication/Medical Necessity Medication require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Non-Formulary/Medical Necessity medications all of the following criteria must be met:

- The requested medication has a diagnosis that is:
 - an FDA-approved indication or
 - a medically accepted indication that is supported by nationally recognized compendia
- 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 medically necessary/non-formulary 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
- 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.
- Members stabilized on a(n) antidepressant, antipsychotic, anticonvulsant, Cytokine and CAM medication, HAE medication, HIV medication, Hepatitis C antiviral, oral immunosuppressive, MS medication, oncology medication, pancreatic enzyme, PAH medication, stimulant (and related agent), idiopathic pulmonary fibrosis (IPF) agent, antiparkinson's agent, thalidomide and derivative, and/or ulcerative colitis agent will not be required to try and fail formulary alternatives.
 - 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.



NON-FORMULARY MEDICATION/ MEDICAL NECESSITY MEDICATION PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date Medication Initiated:

Billing Information

This medication will be billed: at a pharmacy **OR**
 medically (if medically please provide a 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)

Diagnosis: _____ **ICD-10 Code:** _____

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)

Is the Member currently or recently hospitalized? Yes <input type="checkbox"/> No <input type="checkbox"/>	Date of Discharge:
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Additional Clinical or Supporting Information: Please include office notes, lab data, and other supporting medical literature.

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? Yes No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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