



Checklist for **Formulary Exception Request Letter**

A formulary exception is a type of coverage determination that is used when a medicine is not included on a health plan's formulary (list of drugs) or is subject to an NDC block. A **Formulary Exception Request Letter** is a written request asking that the restriction placed on a specific medicine be released as it is medically appropriate and necessary for the patient's treatment. Out-of-network providers may seek a provider exception using this process, especially for patients being treated in the hospital.

A key step in the process is to review the insurer's website or to contact the insurer's customer service for specific forms that may be used when making a formulary exception request.

Note: Many insurers use a Pharmacy Benefits Manager (PBM) for managing patient prescription benefits. Remember that when a prescriber or patient is requesting a formulary exception request, he or she may be communicating with the PBM and not the insurer.

The checklist below highlights items and information that may be needed to obtain a formulary exception from an insurer:

The checklist is neither medical guidance nor a suggestion that you submit an appeal. The information provided on this checklist is general in nature and is not intended to be conclusive or exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding appropriate care and treatment of each patient.

✓ **Completed formulary exception request form(s)**

If required, complete and submit the formulary exception request form to the insurer. Formulary exception forms can be obtained through the insurer's website or by contacting the insurer's customer service.

✓ **Formulary exception letter that includes:**

- **Patient Information**
 - Full name, date of birth, insurance ID number and group number, and other relevant information
- **Physician and facility information**
 - Name, provider ID number, and tax ID number
- **Main reason for formulary exception request**
 - Include medicine strength, frequency, expected length of treatment, quantity, days of supply, and route of administration (if necessary)
- **Rationale for treatment**
 - Insert a clear, summary statement for the reason(s) for medicine/service
 - Include trial data supporting the FDA approval of the requested treatment, as well as the medicine's administration and dosing information
- **Summary of the patient's diagnosis**
 - Diagnosis (ICD-10-CM) and date of diagnosis
 - Patient medical records
 - Diagnostic test results and imaging results
 - Current severity of the patient's condition, including any comorbidities or intolerance to other therapies
- **Summary of the patient's history**
 - Previously administered treatment(s)/procedure(s) and dates
 - Response to the intervention(s)
 - Recent symptoms and condition
 - Recent imaging results and pathology reports showing disease progression
- **Physician opinion of the patient's prognosis or disease progression**

Note: Exercise medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

✓ **Additional relevant information supporting the requested treatment, such as:**

- **Product prescribing information and NDC**
- **Peer-reviewed journal articles or clinical practices referencing nationally recognized guidelines (eg, ASCO, NCCN)**

For expedited requests, adequate information should be provided to support the urgent nature of the request.

ASCO, American Society of Clinical Oncology; ICD-10-CM, International Classification of Diseases, 10th edition, Clinical Modification; NCCN, National Comprehensive Cancer Network; NDC, National Drug Code.