

Medical Exception Request Checklist



A general checklist for the submission of a **medical exception request** (a request asking a health plan to cover a medication that’s not on formulary, often needed for new-to-market drugs when formal coverage determinations have not yet been established by the plan).

Key information to consider including:

CLEAR CHECKLIST

PATIENT INFORMATION	☐ Patient’s full name ☐ Date of birth ☐ Insurance ID number ☐ Group number	WHY: Allows the health plan to quickly identify the patient and policy.
PROVIDER INFORMATION	☐ Prescribing provider's name ☐ Practice/facility name ☐ Contact details ☐ NPI (or provider ID)	WHY: Informs the insurer of who is making the request and how to reach your office.
MEDICATION & REQUEST DETAILS	☐ Clearly state your request.	WHY: Ensures the health plan knows exactly which medication and regimen you are requesting coverage for. KEY CONSIDERATION: For a formulary exception, list medication details, such as: • Drug name, strength, dosing frequency, expected treatment duration, etc.
DIAGNOSIS & CLINICAL RATIONALE	☐ Patient’s diagnosis (include any ICD-10 code[s]) ☐ Concise explanation of why the requested medication is medically necessary.	KEY CONSIDERATION: Describe why this treatment is essential for the patient’s condition. EXAMPLE: "[Drug X] is the appropriate therapy given the patient’s specific needs".
PRIOR THERAPY HISTORY & OUTCOMES	List any previous treatments tried for the condition, including: ☐ Medication names ☐ Dosages ☐ Treatment durations ☐ Outcomes/reasons for discontinuation	WHY: Proves to the health plan that covered alternatives have been exhausted or are not suitable. EXAMPLES: "Patient tried [Drug X] for 3 months with no improvement" "Patient had an adverse reaction to [Drug Y]"

◀ GO BACK

SUPPORTING DOCUMENTATION

- ☐ Attach key medical documents that back up your request.

WHY: Provides objective evidence to strengthen the case for the exception.

KEY CONSIDERATION: Consider including the following documents:

- **Medication’s prescribing information**, including the **Dosage and Administration** section
 - SUNLENCA® (lenacapavir 300 mg) tablets oral loading dose serves as the loading dose in combination with BIXLENVO for virologically suppressed (VS) patients, consistent with the BIXLENVO prescribing information (PI)
- Recent **chart notes, relevant lab results or test reports, imaging results, and specialist consults**

If applicable, you may also want to include:

- **Clinical guidelines or literature** that support using the requested medication for the patient’s scenario

SUBMISSION DETAILS

- ☐ Follow the health plan’s requirements for submission.
- ☐ Check if a specific exception request form or online portal is required; if so, use the correct form and fill it out completely.

WHY: Incomplete requests can cause delays.

KEY CONSIDERATION: If there is no special form:

- Compose a detailed **Letter of Medical Exception** on your practice’s letterhead
 - To view and/or download a sample letter, visit our Resources page at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com)
 - Address the letter to the health plan’s medical review department or Medical Director
 - Include all **relevant details** and **attachments**.
 - Double-check for **accuracy and completeness** before sending

FOLLOW-UP

- ☐ Keep track of the plan’s response timeline

WHY: Many insurers make their decision within a set period (eg, **within 30 days** for an exception request)

KEY CONSIDERATION:

- If you don’t receive a timely answer, **contact the plan to check status**
- **If the exception is denied**, be prepared to discuss next steps (such as filing an appeal or exploring other support options) with the patient and the plan



Why Are These Details Important?

Each item above addresses **information health plans commonly require** in a medical exception review. Providing this information up front helps **demonstrate the medical necessity** of the new medication and ensures the request is processed efficiently. This does not guarantee approval, but a comprehensive, well-documented request can *significantly* improve the chances of a successful medical exception.

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