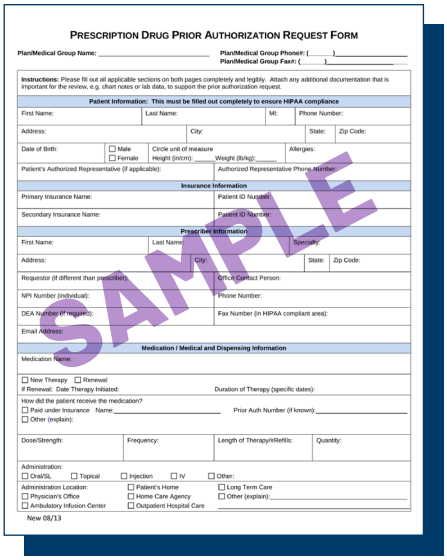
Prior Authorization Checklist

When new medications are approved by the FDA for the treatment of rare diseases, the coverage-approval process often requires healthcare providers to submit a **prior authorization (PA) request** to the patient's insurer before initiating treatment.

Healthcare providers may consider the following steps when seeking coverage approval:



PRESCRIPTION DRUG PRIOR AUTHORIZATION REQUEST FORM

Plan/Medical Group Name: _____ Plan/Medical Group Phone#: (_____)_____
Plan/Medical Group Fax#: (_____)_____

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization request.

Patient Information: This must be filled out completely to ensure HIPAA compliance

First Name: | Last Name: | MI: | Phone Number:
Address: | City: | State: | Zip Code:
Date of Birth: | ☐ Male ☐ Female | Circle unit of measure Height (in/cm): _____ Weight (lb/kg):_____ | Allergies:
Patient's Authorized Representative (if applicable): | Authorized Representative Phone Number:

Insurance Information

Primary Insurance Name: | Patient ID Number:
Secondary Insurance Name: | Patient ID Number:

Prescriber Information

First Name: | Last Name: | Specialty:
Address: | City: | State: | Zip Code:
Requestor (if different than prescriber): | Office Contact Person:
NPI Number (individual): | Phone Number:
DEA Number (if required): | Fax Number (in HIPAA compliant area):
Email Address:

Medication / Medical and Dispensing Information

Medication Name:

☐ New Therapy ☐ Renewal
If Renewal: Date Therapy Initiated: | Duration of Therapy (specific dates):

How did the patient receive the medication?
☐ Paid under Insurance Name:_____ | Prior Auth Number (if known):_____
☐ Other (explain):

Dose/Strength: | Frequency: | Length of Therapy/#Refills: | Quantity:

Administration:
☐ Oral/SL ☐ Topical ☐ Injection ☐ IV ☐ Other:
Administration Location:
☐ Physician's Office ☐ Patient's Home ☐ Long Term Care
☐ Ambulatory Infusion Center ☐ Home Care Agency ☐ Other (explain):_____
☐ Outpatient Hospital Care

New 08/13

SAMPLE

SAMPLE PA REQUEST FORM

Review each insurer's policies and processes regarding prior authorization

Many insurers maintain specific PA policies for newly approved drugs. In general, PA requirements vary by insurer and can be required for any complex treatment or prescription.

Complete and submit a PA request form

Prior authorization requests can often be submitted directly through an insurer's website or initiated via downloadable forms, although in some instances it may be necessary to contact the insurer directly and request a form.

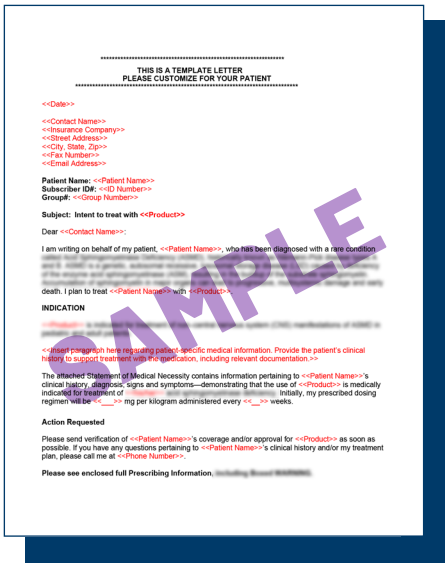
Provide a letter of intent (LOI) to treat

Since a newly launched medication might not yet be on formulary, it may be helpful to provide an LOI that reports:

- **The medication's indication, contraindications, and safety information**
- **The planned dosing regimen**
- **The intended start date of therapy**

The letter should also request immediate action.

The recommendations offered in this document do not guarantee approval of prior authorization requests or reimbursement, nor should they be construed as medical advice. Always consult with patients' insurers/PBMs regarding specific requirements for PA submission.



THIS IS A TEMPLATE LETTER
PLEASE CUSTOMIZE FOR YOUR PATIENT

<<Date>>

<<Contact Name>>
<<Insurance Company>>
<<Street Address>>
<<City, State, Zip>>
<<Fax Number>>
<<Email Address>>

Patient Name: <<Patient Name>>
Subscriber ID#: <<ID Number>>
Group#: <<Group Number>>

Subject: Intent to treat with <<Product>>

Dear <<Contact Name>>:

I am writing on behalf of my patient, <<Patient Name>>, who has been diagnosed with a rare condition, [redacted]. I plan to treat <<Patient Name>> with <<Product>>.

INDICATION

[redacted]

<<Insert paragraph here regarding patient-specific medical information. Provide the patient's clinical history to support treatment with the medication, including relevant documentation.>>

The attached Statement of Medical Necessity contains information pertaining to <<Patient Name>>'s clinical history, diagnosis, signs and symptoms—demonstrating that the use of <<Product>> is medically indicated for treatment of [redacted]. Initially, my prescribed dosing regimen will be <<___>> mg per kilogram administered every <<___>> weeks.

Action Requested

Please send verification of <<Patient Name>>'s coverage and/or approval for <<Product>> as soon as possible. If you have any questions pertaining to <<Patient Name>>'s clinical history and/or my treatment plan, please call me at <<Phone Number>>.

Please see enclosed full Prescribing Information, [redacted]

SAMPLE

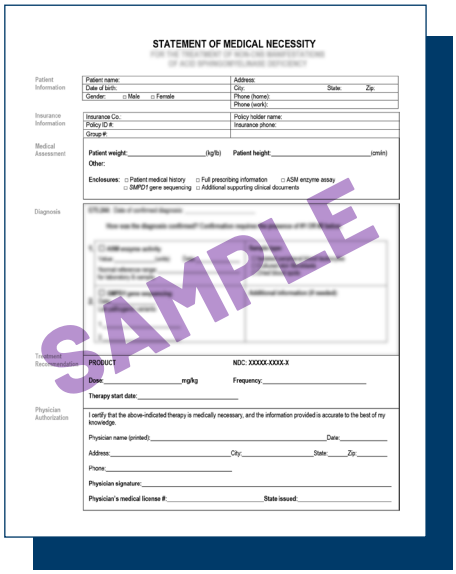
SAMPLE LETTER OF INTENT TO TREAT

Prior Authorization Checklist (cont'd)

Include a statement of medical necessity (SMN)

An SMN can help to demonstrate that a treatment plan is medically necessary. The statement should include:

- **Patient information such as name, date of birth, policy number, and group number**
- **The appropriate ICD-10-CM diagnostic code**
- **Relevant clinical data supporting the diagnosis**
- **The medication's brand name, dosing requirements, and NDC number**
- **The healthcare provider's name, office address, and contact information (even if already provided on the completed PA request form)**
- **Any other relevant information, such as a HCPCS procedure code**


STATEMENT OF MEDICAL NECESSITY

Patient Information

Patient name:
Date of birth:
Gender: □ Male □ Female
Address:
City: State: Zip:
Phone (home):
Phone (work):

Insurance Information

Insurance Co.:
Policy ID #:
Group #:
Policy holder name:
Insurance phone:

Medical Assessment

Patient weight: (kg/lb) Patient height: (cm/in)
Other:
Enclosures: □ Patient medical history □ Full prescribing information □ ASM enzyme assay
□ SMPD1 gene sequencing □ Additional supporting clinical documents

Diagnosis

Treatment Recommendation

PRODUCT: NDC: XXXXX-XXXX-X
Dose: mg/kg Frequency:
Therapy start date:

Physician Authorization

I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.
Physician name (printed): Date:
Address: City: State: Zip:
Phone:
Physician signature:
Physician's medical license #: State issued:

SAMPLE

SAMPLE STATEMENT OF MEDICAL NECESSITY

If prior authorization is denied

In the event a PA request is denied, healthcare providers have the option to appeal. To prepare for an appeal:

- **Revisit the insurer's submission requirements and confirm the initial claim was submitted correctly**
- **Review the insurer's appeal process and deadlines**
- **Download (or call to request) an appeal form and submit promptly**

For further assistance, contact your Sanofi representative, or call CareConnectPSS, Sanofi's patient support service, at 1-800-745-4447 (option 3) to speak to a Case Manager.

The recommendations offered in this document do not guarantee approval of prior authorization requests or reimbursement, nor should they be construed as medical advice. Always consult with patients' insurers/PBMs regarding specific requirements for PA submission.

sanofi

MAT-US-2203536-v1.0-08/2022