Sample Letter of Medical Necessity
BD-148457

Introduction:

Many payors require that a prescribing physician or health care practitioner document a patient's medical necessity for insurance coverage for a medical device for treatment.

The following is intended as a sample *Letter of Medical Necessity* that outlines common information a payor may request. You can share this sample Letter of Medical Necessity with your physician or health care practitioner as an example. Your physician or health care provider (also known as the prescriber) is responsible for the content and submission of this letter and should customize all bracketed information in blue with the appropriate payor, office, and patient information.

A prescribing physician / health care practitioner should be aware that medical records must be included and be consistent with the information outlined in the Letter of Medical Necessity. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of this letter does not guarantee coverage for the product. The prescriber should refer to the Important Safety Information in the full *Information for Use* when determining whether the product is medically appropriate for a patient.

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[Date]

[Name of Pharmacy Director / Payer Contact]

[Contact Title]

[Name of Health Insurance Company]

[Address, City, State, Zip Code]

RE: Coverage for [Product Name]

Patient: [Patient Name]

Date of Birth: [Date]

Diagnosis: [Diagnosis], [ICD-10-CM]

Group/Policy Number: [Number]

Policyholder: [Policyholder Name]

To Whom It May Concern:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity to treat their [Diagnosis] with [Product Name].

This letter serves to summarize the supporting medical records which are enclosed. The included medical records document my patient's medical history, diagnosis and treatment rationale. Please refer to the [List any Enclosures. Medical records must be included and be consistent with the information outlined in the Letter of Medical Necessity] enclosed with this letter.

Summary of [Patient Name] Medical History and Diagnosis

[Patient Name] is [Age] years old, has been diagnosed with [Diagnosis (HCPCS)] [ICD-10-CM] on [Date] and has been in my care since [Date].

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[Provide a discussion of the patient's clinical history, current symptoms, diagnoses and conditions, any potential contraindications, and any relevant laboratory test results, highlighting the factors leading you to recommend use of the product]

Rationale for Treatment

[Include your clinical rationale and reasons for prescribing the product]

For simplification, [Patient Name] has been diagnosed with the following documented signs and symptoms:

- Patient has acute urinary retention or bladder outlet obstruction[1]
- Critically ill, in need of accurate measurements of urinary output[1]
- Perioperative use for selected surgical procedures[1]:
  - Patient undergoing urologic surgery or other surgery on contiguous structures of the genitourinary tract[1]
  - Anticipated prolonged duration of surgery[1]
  - Patient anticipated to receive large-volume infusions or diuretics during surgery[1].
  - Need for intraoperative monitoring of urinary output[1]
- Incontinent, need for assistance in healing of open sacral or perineal wounds[1]
- Requires prolonged immobilization *(e.g., potentially unstable thoracic or lumbar spine, multiple traumatic injuries such as pelvic fractures)*[1]
- To improve comfort for end-of-life care if needed[1]
- Voiding difficulties due to neurological disorder / paralysis / loss of sensation affecting urination (requires maintaining a continuous outflow of urine)[1]
- Loss of skin integrity secondary to incontinence[1]
- Other

The following are complications for which my patient may be at risk in the absence of recommended treatment:

- Cystitis[2]

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- Recurrent hospitalization[3]
- Kidney stone disease[4]
- Urethral stricture[5]
- Antimicrobial resistance[6]
- Increased morbidity & mortality (pyelonephritis, chronic renal disease, urosepsis)[2,7,8]
- Cellulitis[2]
- Decreased physical activity and libido[2]
- Depression[2]
- Increased caregiver burden[2]
- Increased risk of falls and subsequent fractures[2]
- Mechanical failure (leak)[2]
- Pressure ulcers[2]
- Renal dysfunction secondary to obstructive uropathy[2]
- Sexual dysfunction[2]
- Social isolation[2]
- Urethral erosion[2]
- Worsening of urinary incontinence after surgical intervention[2]
- Other

In summary, in my clinical judgment [Optional: may add information regarding expertise and how long you have been treating patient] the following medical device is deemed medically necessary and reasonable to treat [Patient Name's] [Diagnosis], and I ask you to please consider coverage of [Product Name] on [Patient Name's] behalf. The anticipated duration of treatment is [add duration of treatment or "lifetime" if chronic]. Please do not hesitate to call me at [Phone Number] if you have any questions or if you require additional information.

- Intermittent Urinary Catheters with Close-System kits (HCPCS A4353) (Note: Check for annual updates to the CPT and HCPCS code lists used by Medicare

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https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52521&ContrID=140)[9]

Thank you for your attention to this matter.

Sincerely,

[Physician Name and Credentials] [NPI Number]

Documents are provided for educational and informational purposes only and do not guarantee coverage or payment. Coverage and payment policies change over time. The accuracy of the information is not guaranteed and should be confirmed with the payor.

References:

1. Centers for Disease Control and Prevention. Guideline for Prevention of Catheter-Associated Urinary Tract Infections (CAUTI). CDC; 2009. Available at: https://www.cdc.gov/infection-control/media/pdfs/Guideline-CAUTI-H.pdf. Accessed March 26, 2025.
2. National Kidney and Urologic Diseases Information Clearinghouse. Pyelonephritis: Kidney Infection. National Institutes of Health; April 2012
3. Ioannou P, Plexousaki M, Dimogerontas K, et al. Characteristics of Urinary Tract Infections in Older Patients in a Tertiary Hospital in Greece. Geriatr Gerontol Int. 2020;20:1228-1233.
4. Ripa F, Pietropaolo A, Montanari E, Hameed BMZ, Gauhar V, Somani BK. Association of Kidney Stones and Recurrent UTIs: the Chicken and Egg Situation. A Systematic Review of Literature. Curr Urol Rep. 2022;23:165-174.
5. Verla W, Oosterlinck W, Spinoit AF, Waterloos M. A Comprehensive Review Emphasizing Anatomy, Etiology, Diagnosis, and Treatment of Male Urethral Stricture Disease. Biomed Res Int. 2019;2019:1-20.

6. Ku JH, Tartof SY, Contreras R, et al. Antibiotic Resistance of Urinary Tract Infection Recurrences in a Large Integrated US Healthcare System. J Infect Dis. 2024;230(6):e1344-e1354.
7. Lohr JW, Gowda A, Nzerue CM. Chronic Pyelonephritis. Medscape. June 19, 2023.
8. Dreger NM, Degener S, Ahmad-Nejad P, Wöbker G, Roth S. Urosepsis—Etiology, Diagnosis, and Treatment. Dtsch Arztebl Int. 2015;112:837-848.
9. Centers for Medicare & Medicaid Services. Urological Supplies - Policy Article (A52521). https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52521. Published October 1, 2015. Revised April 1, 2023. Accessed September 3, 2025. [www.cms.gov]