DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

Urological Supplies: Intermittent Catheters

REQUIRED DOCUMENTATION

- ☐ **Standard Written Order** that includes:
  - ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
  - ○ General description of the item
    - ☐ The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently ordered supplies that are separately billed (List each separately)
  - ○ Quantity to dispense, if applicable
  - ○ Treating Practitioner Name or NPI
  - ○ Treating practitioner's signature
  - ○ Order Date
- ☐ Treating Practitioner's signature on the written order meets **CMS Signature Requirements** 100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4.

NOTE: Suppliers should not submit claims to the DME MAC prior to obtaining a standard written order. Items billed to the DME MAC before a signed and dated standard written order has been received must be submitted with modifier EY.

- ☐ **Refill Request**

For dates of service on and after January 1, 2024	
Items Were Obtained In Person at a Retail Store	**Delivered Refill Communications**
☐ Signed delivery slip or copy of itemized sales receipt ☐ Delivery slip/receipt should indicate items were picked up at store front	☐ Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Date of Request ☐ Description of each item requested ☐ Documentation of affirmative response indicating a need for the refill ☐ Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply ☐ Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

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☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice	Delivery to Nursing Facility on Behalf of a Beneficiary
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date	☐ Documentation demonstrating delivery of the item(s) to the facility by the supplier or delivery entity; and, ☐ Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the beneficiary. The quantities delivered and used by the beneficiary must justify the quantity billed.

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

Medical Records for all HCPCS codes

☐ Medical records verify that the beneficiary has permanent urinary incontinence or permanent urinary retention.

☐ Clinician signature(s) on medical records meets **CMS Signature Requirements** 100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4

Claims for Coude or Curved Tip Catheters (HCPCS Code A4352)

☐ The beneficiary's medical record documents the medical necessity for this type of catheter.

Claims for Sterile Intermittent Catheter Kits (HCPCS Code A4353)

☐ The beneficiary meets one of the following criteria:

- ○ The beneficiary resides in a nursing facility.
- ○ The beneficiary is immunosuppressed (examples are not all-inclusive):
  - ☐ On a regimen of immunosuppressive drugs post-transplant,
  - ☐ On cancer chemotherapy,
  - ☐ Has AIDS,
  - ☐ Has a drug-induced state such as chronic oral corticosteroid use,
  - ☐ Other.
- ○ The beneficiary has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization.
- ○ The beneficiary is a spinal cord injured female with neurogenic bladder who is pregnant (qualifies only for the duration of the pregnancy).

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- ○ The beneficiary has had distinct, recurrent urinary tract infections while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12-months prior to the initiation catheterization with the sterile intermittent catheters kits.

☐ Signatures on documents meet CMS Signature Requirements

☐ Clinician signature(s) on medical records meets **CMS Signature Requirements**
100-08 Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4

ATTENTION

A beneficiary would be considered to have a urinary tract infection if they have a urine culture with greater than 10,000 colony forming units of a urinary pathogen AND concurrent presence of one or more of the following signs, symptoms or laboratory findings:

- Fever (oral temperature greater than 38° C [100.4° F]);
- Systemic leukocytosis;
- Change in urinary urgency, frequency, or incontinence;
- Appearance of new or increase in autonomic dysreflexia (sweating, bradycardia, blood pressure elevation);
- Physical signs of prostatitis, epididymitis, orchitis;
- Increased muscle spasms; or
- Pyuria (greater than 5 white blood cells [WBCs] per high-powered field).

REMINDERS

- A4353 should not be used for billing if the components are packaged separately rather than together as a kit. Separately provided components do not provide the equivalent degree of sterility achieved with an A4353. If separate components are provided instead of a kit (A4353) they will be denied as not reasonable and necessary.
- Suppliers must add a KX modifier to a catheter, an external urinary collection device, or a supply used with one of these items only if both 1 and 2 are met:
  1. The statutory benefit criteria described in the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the Policy Article are met, and
  2. The applicable reasonable and necessary (R&N) criteria described in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of the LCD are met.
- If all the criteria in the Nonmedical Necessity Coverage and Payment Rules section of the Policy Article are not met, the GY modifier must be added to the code.
- If all of the applicable R&N criteria in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section in the related LCD have not been met, a GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity (R&N) denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.
- Claims lines billed without a KX, GA, GY or GZ modifier will be rejected as missing information.
- Refer to the Supplier Manual for more information on documentation requirements.

ONLINE RESOURCES

- **Urological Supplies LCD and Policy Article**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/LCDinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/LCDinfo.html
- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html

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NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.