The supplier must be able to provide all of these items on request:

- **Standard Written Order (SWO)**
- **Beneficiary Authorization**
- **Proof of Delivery (POD)**
- **Refill Requirements**
- **Continued Need**
- **Continued Use**
- Medical records from treating practitioner as noted below

**Medical Records should contain:**

Urinary catheters and external urinary collection devices

- Medical records support the beneficiary has permanent urinary incontinence or permanent urinary retention that is not expected to be medically or surgically corrected within 3 months.

Indwelling catheters (A4331 – A4316, A4338 – A4346)

- No more than one catheter change per month for routine catheter maintenance
- Non-routine indwelling catheter changes
  - Medical records substantiate medical necessity for non-routine catheter changes such as:
    - Catheter is accidentally removed (e.g., pulled out by beneficiary)
    - Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter)
    - Catheter is obstructed by encrustation, mucous plug, or blood clot
    - History of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month

Specialty indwelling catheter (A4340) or all silicone catheter (A4344, A4312, or A4315)

- Criteria for an indwelling catheter (above) are met; **and**
- Medical records justify the need for that catheter such as;
  - Recurrent encrustation; **or**

The content of this document was prepared as an educational tool and is not intended to grant rights or impose obligations. Use of this document is not intended to take the place of either written law or regulations. Suppliers are reminded to review the Local Coverage Determination and Policy Article for specific documentation guidelines.
- Inability to pass a straight catheter; or
- Sensitivity to latex

3-Way indwelling catheter either alone (A4346) or with other components (A4313, A4316)

- Medical records support continuous catheter irrigation is medically necessary
  - There is a history of obstruction of the catheter; and
  - Patency of the catheter cannot be maintained by intermittent irrigation in conjunction with reasonable and necessary catheter changes.

Non-routine Changes of Urinary Drainage Collection System (A4314 – A4316, A4354, A4357, A4358, A5102, A5112)

- Medical records support the necessity for non-routine changes such as:
  - Obstruction
  - Sludging
  - Clotting of blood
  - Chronic, recurrent, urinary tract infections

Leg Bags (A4358 or A5112)

- Medical records support the beneficiary is ambulatory or chair or wheelchair bound.

Intermittent Irrigation (A4320, A4322, A4217) of Indwelling Catheters

- Medical records show irrigation is being performed on a non-routine basis due to the presence of an acute obstruction in the catheter.

Continuous Irrigation of Indwelling Catheters [3-way Foley catheter (A4313, A4316, A4346), irrigation tubing (A4355), and sterile water/saline (A4217)]

- History of obstruction of the catheter; and
- Patency of the catheter cannot be maintained by intermittent irrigation in conjunction with reasonable and necessary catheter changes; and
- Record substantiates the medical necessity of catheter irrigation and in particular continuous irrigation as opposed to intermittent irrigation; and
- Record indicates the rate of solution administration and the duration of need.

Intermittent Catheterization (A4351, A4352, A4332, or A4353)

- Basic coverage criteria are met; and
- Beneficiary or caregiver can perform the procedure.

Sterile Intermittent Catheterization (SIC) Kits (A4353)

- Medical records support the beneficiary requires catheterization and meets one (1) of the following:
  - Beneficiary resides in a nursing facility; or
  - Beneficiary is immunosuppressed: or
- Beneficiary has a radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization; or
- Beneficiary is a spinal-cord injured pregnant female with neurogenic bladder; or
- Beneficiary has had distinct, recurrent UTI's while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant (A4332) twice within the 12-month period prior to initiation of SIC.

  - Urine culture with >10,000 colony forming units of a urinary pathogen and concurrent presence of at least one (1) of the following:
    - Fever; or
    - Systemic leukocytosis; or
    - Change in urinary urgency, frequency or incontinence; or
    - Appearance of new or increase in autonomic dysreflexia; or
    - Physical signs of prostatitis, epididymitis, orchitis; or
    - Increased muscle spasms; or Pyuria.

Coude (Curved) Tip Catheter (A4352)

- Medical records support necessity for a curved rather than straight tip catheter (A4351)

External Catheters/Urinary Collection Devices

- Medical records support the beneficiary has permanent urinary incontinence and the external device is used as an alternative to an indwelling catheter

  More Than 35 Male External Catheters (A4349)/Month

    - Medical records support the medical necessity.

Specialty type male external catheters (A4326)

- Medical records support the medical necessity.

Miscellaneous Supplies

- Urethral inserts (A4336)

  - Adult female has stress incontinence; and
  - Basic coverage criteria are met; and
  - Beneficiary or caregiver can perform the procedure.