Intermittent Urinary Catheters HCPCS Code Research

Center for Medicare and Medicaid Services (CMS)

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Executive Summary

The Centers for Medicare and Medicaid Services (CMS) has a long history of code requests resulting in the Healthcare Common Procedure Coding System (HCPCS) codes for intermittent urinary catheters (A4351, A4352, and A4353). Beginning in 2010, requestors submitted six applications to CMS to expand the existing HCPCS Level II code set for intermittent urinary catheters. CMS denied these applications for various reasons, including a lack of clinical evidence to support new codes. As catheter technology continues to evolve, CMS anticipates future requests for code expansion.

The Center for Medicare (CM) within CMS requested that the Health Federally Funded Research and Development Center (FFRDC), operated by MITRE, perform a needs assessment consisting of an environmental scan of commercial and public payer policies to reveal trends in the payer community, and engage clinical experts to provide insight on the standards of care for ordering intermittent urinary catheters. This assessment was combined with a 2023 systematic review of clinical evidence on the impact of intermittent catheters on patient net health outcomes to form a multifactorial assessment of the current state of technology and practice for intermittent catheters. Findings from this holistic assessment will help inform CM's future responses to HCPCS Level II intermittent urinary catheters code requests.

Key Findings:

- The most supported code addition based on research and evidence is for hydrophilic coating. There is good evidence that, for some patients, hydrophilic catheters may reduce the incidence of a urinary tract infection (UTI). Also, a hydrophilic coating code could streamline patient access through supplier fulfillment and claims processing improvements.
- A new code could allow insurers to further automate claims processing by specifying in claims processing edits the appropriate conditions under which hydrophilic catheters are covered. Improving access and shortening the amount of time it takes for patients to receive catheters could save insurers money in claims processing, avoid claims appeals and may generate better patient outcomes (e.g., fewer urinary tract infections (UTIs)).
- While new codes or updates to existing codes may enable suppliers to differentiate specific catheter types appropriate for defined patient populations, for most of the potential codes considered there is a lack of evidence to support performance differentiation when compared to current catheter codes. Additional codes, while more descriptive, would generally not ameliorate the patient access issues.
- Specifics such as length, gender, pediatric, or adult are often useful distinctions for the supplier. However, these distinctions are functionally equivalent within the same catheter type and further specificity through coding may not benefit claims processing.
- Half the commercial payers assessed, and all public payers assessed used a limited number of secondary codes to augment the available HCPCS Level II codes for catheters.
- Most insurers we reviewed are deeming catheters as durable medical equipment (DME) or Durable Medical Equipment, Prosthetics/Orthotics & Supplies (DMEPOS), which may affect its coverage for certain insurers; this is not aligned with the Medicare determination of catheters as Prosthetics/Orthotics and Supplies (POS).

1 Needs Assessment for Potential HCPCS Level II Codes

MITRE conducted a holistic needs assessment for additional HCPCS Level II codes to describe intermittent catheters. This included reviewing synthesized clinical evidence for intermittent catheters, performing an environmental scan of multiple types of insurers/payors catheter policies, and engaging clinicians to provide insight on the standards of care for ordering intermittent catheters. MITRE identified seven criteria to apply to the body of evidence compiled through the needs assessment. These criteria reflect the information that may be presented in a HCPCS Level II code application. MITRE applied these criteria to develop findings that can inform decisions on future HCPCS Level II coding requests.

Table 1-1. Description of Assessment Criterion

Criterion	Brief Description
Previous Request	Details if CMS has reviewed a request for this code descriptor within the HCPCS new code application process
Clinical Evidence	Refers to the results in the previously performed systematic review
Industry Coding Practices	Summarized results of the environmental scan of insurers and payors
Manufacturer and Supplier Offerings	Summarized overview of manufacturer and supplier catheter offerings
Clinical Ordering Practices	Summarized results of the inputs from the expert clinicians
Patient Receives Ordered Catheter	Findings related to the supply ordering process and alignment with the standard written order
Administrative and Processing Efficiency	The potential for improved claims processing by insurers and payors if new codes were introduced

1.1 Summary of Findings

The assessment results are detailed in the below tables. There are few clearly supported potential HCPCS Level II code additions across all domains investigated. The most supported code addition is for hydrophilic coating. Catheters with hydrophilic coatings have clinical evidence supporting their use as well as some demonstrated need by commercial insurers. A hydrophilic coating code could streamline ordering and supplying and potentially increase administrative efficiency in claims processing.

While other potential codes may enable suppliers to differentiate specific catheter types appropriate for defined patient populations (as compared to the existing code set), there is a lack of a solid evidence base to support performance differentiation from current catheter codes. The level of specificity often cited as needed in the code request applications for intermittent catheters can be accommodated in the current standard written order from the prescribing provider. The findings further elucidate the other factors considered for justification of additional coding with summaries of the assessment results.

Specific information such as length, gender, pediatric, or adult (which often refers to French size or diameter) are useful distinctions for the supplier. However, these distinctions are functionally equivalent within the same catheter type (e.g., hydrophilic catheter) and further specificity through coding may not provide benefits in claims processing because costs are typically equivalent across a size range. If additional specificity for this information was desired, applying modifiers to the existing codes may provide an alternate solution.

Table 1-2. Straight Tip, with or without coating (A4351)

Category	Finding
Previous Request	2014, 2015, 2017, Coloplast's Hydrophilic. 2022, AA Homecare 19 codes
Clinical Evidence	Tip configuration addresses anatomical differences
Industry Coding Practices	Referenced by 7 out of 14 commercial payers and 4 out of 4 public payers assessed
Manufacturer & Supplier Offerings	Commonly used to group catheters with a straight tip
Clinical Ordering Practices	HCPCS codes are not necessary for ordering catheters
Patient Receives Ordered Catheter	Neutral impact on patients/current code
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits

Table 1-3. Coudé (curved) Tip, with or without coating (A4352)

Category	Finding
Previous Request	2014, 2015, 2017, Coloplast's Hydrophilic. 2022, AA Homecare 19 codes
Clinical Evidence	Tip configuration addresses anatomical differences
Industry Coding Practices	Referenced by 7 out of 14 commercial payers and 4 out of 4 public payers assessed
Manufacturer & Supplier Offerings	Commonly used to group catheters with a curved tip
Clinical Ordering Practices	With increased BMI people, curve tip (coudé) catheters may be used to access a retracted urethra in both men and women (also see A4351)
Patient Receives Ordered Catheter	Neutral impact on patients/current code
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits

Table 1-4. Kit, with insertion supplies (A4353)

Category	Finding
Previous Request	2010, Hollister's No touch. 2014, 2015, Coloplast Hydrophilic. 2022, Hollister's No touch. 2022, AA Homecare 19 codes
Clinical Evidence	Clinical experience informed that more complex catheter packaging and supplies may impact understanding of use which can affect health outcomes
Industry Coding Practices	Referenced by 7 out of 14 commercial payers and 4 out of 4 public payers assessed

Category	Finding
Manufacturer & Supplier Offerings	Commonly used to group catheters with a kit to facilitate a clean insertion
Clinical Ordering Practices	Supplementary information may need to be provided to the supplier for catheter kits (i.e., proof of UTIs or other criteria). Also see A4351.
Patient Receives Ordered Catheter	Neutral impact on patients/current code
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits

Table 1-5. Hydrophilic Coating

Category	Finding
Previous Request	2014, 2015, 2017, Coloplast's Hydrophilic
Clinical Evidence	Review found evidence that hydrophilic coating can reduce the risk of UTIs and hematuria
Industry Coding Practices	Referenced by 0 out of 14 commercial and 2 out of 4 public payers assessed
Manufacturer & Supplier Offerings	Hydrophilic coating dominates their inventory
Clinical Ordering Practices	People with a history of UTI's or who develop UTI's while on IC may require hydrophilic catheters or self-contained systems
Patient Receives Ordered Catheter	Appropriate patients with history of UTIs and prior to use of closed systems
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits

Table 1-6. Other Coating

Category	Finding
Previous Request	None
Clinical Evidence	Evidence was insufficient to determine if other coating impacts health outcomes
Industry Coding Practices	N/A
Manufacturer & Supplier Offerings	Commonly referred to as pre-lubricated
Clinical Ordering Practices	Nurse assessments in the office have determined that quality of life of the patient requires a change to a pre-lubricated style catheter
Patient Receives Ordered Catheter	Neutral impact to patients
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits

Table 1-7. Catheter Length

Category	Finding
Previous Request	None

Category	Finding
Clinical Evidence	Not assessed − did not identify studies on length but clinical experts recommended additional studies on this topic
Industry Coding Practices	None of the commercial (0 of 14) or public payers (0 of 4) referenced non-standard coverage pertaining to catheter length in their policies
Manufacturer & Supplier Offerings	Included in manufacturer and supplier catalogs
Clinical Ordering Practices	Anatomic considerations other than those associated with gender help determine appropriate length
Patient Receives Ordered Catheter	Neutral impact to patients
Administrative and Processing Efficiency	Current codes sufficient

Table 1-8. Patient Gender

Category	Finding
Previous Request	None
Clinical Evidence	Not assessed − did not identify studies on gender, but clinical experts believed sex leads to differences in health outcomes
Industry Coding Practices	Mentioned by commercial payers only (3 out of 14); two of the three references are pertaining to use of coudé (curved) tip catheters
Manufacturer & Supplier Offerings	Included in manufacturer and supplier catalogs
Clinical Ordering Practices	Also see "Catheter Length" section
Patient Receives Ordered Catheter	Neutral impact to patients
Administrative and Processing Efficiency	Current codes sufficient

Table 1-9. Adult/Pediatric

Category	Finding
Previous Request	None
Clinical Evidence	Not assessed − did not identify studies on age but clinical experts did not believe age leads to differences in health outcomes
Industry Coding Practices	Pediatric supplies were only specifically mentioned by 1 out of 4 public payers in reference to utilization of modifier code U4 for pediatric supply items generally but the modifier is not specific to catheters
Manufacturer & Supplier Offerings	Included in manufacturer and supplier catalogs
Clinical Ordering Practices	Information is commonly including in written orders
Patient Receives Ordered Catheter	Neutral impact to patients
Administrative and Processing Efficiency	Current codes sufficient

Table 1-10. Grip Sleeve

Category	Finding
Previous Request	2010, Hollister's No touch
Clinical Evidence	Evidence was inconclusive as to whether protective elements influence health outcomes
Industry Coding Practices	N/A
Manufacturer & Supplier Offerings	Sleeves largely available to facilitate insertion as an accessory and not as part of a kit
Clinical Ordering Practices	Catheters with positional aids (grippers, pre lubrication) may also reduce need for assistance with catheter passage
Patient Receives Ordered Catheter	Catheters with grip/sleeve and "no touch" are coded A4353 (Kit). Patients only need the sleeve.
Administrative and Processing Efficiency	Additional specificity in coding could enhance claims processing/automated edits by allowing for distinct procedure code/diagnosis code pairings to be applied through automated claims processing rules/edits.

2 Clinical Evidence Review

MITRE conducted a comprehensive systematic review to assess the evidence base on catheter performance characteristics.

MITRE's review included multiple components. MITRE examined peer-reviewed literature consisting of clinical studies, meta-analyses, systematic reviews, and comparative studies published from 1989 to present. Next, MITRE reviewed evidence that assessed if and how specific intermittent catheter characteristics, such as material, coating, tip configuration, shape, and protective elements, influence health outcomes in patients with chronic urinary retention or incontinence issues. Studies centered on self-performed or caregiver assisted catheterization conducted outside of the medical setting (i.e., at home). After compiling and analyzing the literature, MITRE engaged with clinical experts to assess the quality and strength of evidence and consider their insights.

From its systematic review, MITRE concluded that the evidence base is insufficient to determine that all coatings impact health outcomes, but there was evidence supporting that hydrophilic coating may influence health outcomes. Specifically, it identified studies demonstrating that catheters with hydrophilic coating can reduce the risk of UTIs and hematuria. MITRE could not identify studies that differentiated between hydrophilic coating catheter types (i.e., pre-activated, manually activated) or discern the impact of hydrophilic coating on quality-of-life outcomes.

Further, MITRE could not identify any studies that assessed whether catheter shape, tip configuration (i.e., straight, coudé), or firmness led to differences in patient outcomes. While MITRE identified studies that assessed whether protective elements (i.e., introducer tip, no-touch sleeve) and re-use (vs. single use) catheters influenced health outcomes, the evidence was inconclusive. MITRE also examined whether patient characteristics led to differences in health outcomes, but it could not identify studies that assessed differences by patient age, sex, disease, or condition, or whether administration assistance was present. Despite the lack of literature,

clinical experts believed that sex, assisted administration, and disease or condition influence health outcomes but did not believe age to be a factor.

MITRE's systematic review concluded that the evidence base pertaining to intermittent catheters is lacking and plagued by study design and quality issues. Clinical experts recommended that additional studies separate sensate and neurologically impaired populations as well as male and female patients and should also include longer follow-up periods and assess the time burden associated with care or catheter type. Finally, clinical experts recommended future studies examine three main catheter comparisons: (1) material (PVC vs. non-PVC), (2) design (length, tip type), and (3) coating (hydrophilic, pre-lubricated, standard). Specifically, clinicians noted that studies on catheter length could help determine appropriate patient care.

3 Environmental Scan

MITRE conducted an environmental scan between July and September 2023 that included 14 commercial and four public payers. MITRE assessed specific coding elements – including existing HCPCS Level II codes for intermittent urinary catheters, non-standard catheter coverage, step therapy, and secondary coding – that have been utilized to support past intermittent urinary catheter HCPCS Level II code requests since 2010.

Most payers covered intermittent urinary catheters in their DME or DMEPOS policies. In addition, some insurance providers use NCD 280.1 on DME to inform their policies on intermittent urinary catheters. The NCD defines DME as equipment that can withstand repeated use[1] and provides a list of DME equipment with related coverage conditions. The equipment list states that Medicare does not consider non-reusable catheters to be DME and, therefore, would deny coverage of single-use catheters under the DME policy. Other determinations for the Medicare Program, such as L33803, define intermittent catheters as prosthetics, since they replace a malfunctioning body member. However, the NCD essentially determines that intermittent catheters are not DME, which is different than asserting non-coverage.

3.1 Summary of Findings

The following themes were identified after assessing all payer policies in aggregate. In general, there were no overarching commonalities that either spread across most commercial payers, public payers, or both – apart from existing HCPCS Level II code references. Non-standard catheter references were only made by a subset of the payers assessed and did not indicate a unified approach; references primarily focused on sterile technique. References to special populations – based on gender, age, or underlying health conditions, were made by only a subset of payers and focused, primarily, on coudé (curved) tip catheter use by females. Secondary codes – including modifiers SC, U4, and 25, as well as 9943N AT, 9993N AT, E1399, A4335, and 51701 – were used by half of the commercial payers (7 of 14) and all public payers (4 of 4) assessed; however, there was great variability between codes utilized. Furthermore, mentioning of coding element in policy does not imply direct application to intermittent urinary catheters or coverage.

[1] NCD 280.1 refers only to DME and not prosthetics and orthotics (POS).

- Existing HCPCS Level II Codes*:* Half (7 of 14) of the commercial payers and all (4 of 4) public payers assessed specifically reference the existing HCPCS Level II codes (A4351, A4352, and A4353) in their policy and reference all three codes without exception.
    - *Quantity:* When mentioned, payers limit coverage of supplies for intermittent catheterization to up to 200 items per month (or 600 combined units in any 90-day period for some payers per CMS timeframes and quantities for refills of ongoing supplies). Note: Anthem Health Keepers Plus − Virginia Medicaid limits quantities for each to 180 items per month. Medi-Cal's quantity limits without authorization (and treatment authorization request) are 150 per 27-day period for A4351 and A4352 per their Medical Supplies Billing Codes, Units and Quantity Limits list (see first link in PDF; for A4353 Medi-Cal requires a treatment authorization request and no specific quantity limits are listed.
- Non-standard Catheter Coverage:
    - *Hydrophilic Coating:* Hydrophilic catheters were not specifically mentioned by any commercial payers (0 of 14) but were referenced by two public payers (2 of 4) – Texas and Michigan Medicaid. Texas Medicaid specifies that for hydrophilic catheters, procedure code A4351 must be accompanied with modifier SC (a medically necessary service or supply). Michigan Medicaid identifies additional coverage conditions for hydrophilic catheters and specifies that prior authorization is required. However, Michigan Medicaid does not use unique modifiers or codes to distinguish hydrophilic catheters from other types. Note: While Medi-Cal and the Veterans Affairs Federal Supply Schedule referenced hydrophilic catheters in their list of Contracted Intermittent Catheters spreadsheet and National Acquisition Center MedSurg Catalog respectively, hydrophilic-coated catheters were not expressly mentioned in their policies pertaining coverage conditions or secondary coding.
- *Sterile Technique:* Sterile intermittent catheterization is described in three commercial payer policies (3 of 14) pertaining to medical necessity (i.e., step therapy). While coverage criteria vary by payer, one policy (BlueCross BlueShield of North Dakota − commercial & Medicaid Expansion) specifically includes recurring urinary tract infections after clean intermittent catheterization as one of such criteria for coverage of sterile intermittent catheterization. Only one of the public payer policies (1 of 4) reference sterile technique; Texas Medicaid includes recurring UTIs as one of multiple coverage criteria for sterile intermittent catheterization.
- *Length:* None of the commercial (0 of 14) or public payers (0 of 4) reference non-standard coverage pertaining to catheter length in their policies.
- Special Populations:
- *Gender*: Medical necessity by gender was mentioned by three commercial payers only (3 of 14) – Aetna Commercial, BlueCross BlueShield of North Dakota − commercial & Medicaid Expansion, and UnitedHealthcare − Medicare Advantage. Two out of three references are pertaining to coudé (curved) tip catheters. Coudé catheters are rarely medically necessary for females per the policies, i.e., only when a straight tip catheter cannot be used. An example would be the inability to catheterize with a straight tip catheter. The other reference is

pertaining to sterile catheterization and pregnant females with spinal cord injury with neurogenic bladder (during pregnancy only).

- *Pediatric Population*: Pediatric supplies were only specifically mentioned by one public payer (1 of 4; Michigan Medicaid) in reference to utilization of modifier code U4 and were not specific to catheters.
- *Urinary Tract Infection (UTI)*: Mentioned by two (2 of 14) commercial payers (BlueCross BlueShield of North Dakota − commercial and Medicaid Expansion; UnitedHealthcare – Medicare Advantage) and one (1 of 4) public payer (Texas Medicaid). Both references are pertaining to medical necessity for sterile intermittent catheterization.

- Secondary Codes: Payers that accept and reference secondary codes in their policies include half of the commercial payers (7 of 14) and all public payers (4 of 4). However, reference of secondary codes may not be related to intermittent urinary catheters and does not imply coverage. Codes E1399 and A4335 had the most applicability to either intermittent urinary catheters directly or miscellaneous supplies (including durable medical equipment). References to code E1399 were specific to miscellaneous supplies and are further described in section 4.3.4.5. References to code A4335 were more variable and are further described in section 4.3.4.6; some payers specifically do not cover certain catheter supplies under this code, and other payer references are not specific to catheters.

3.2 Detailed Assessment of Code References in Payer Policies

The following sections describe summary findings from 14 commercial payers and four public payers pertaining to codes referenced in the payer policies assessed (Table 3-1).

Table 3-1. Coding Elements Referenced in Payer Policies

Coding Element Referenced in Payer Policy*	Commercial Payers (Total assessed: 14)	Public Payers (Total assessed: 4)
Intermittent Urinary Catheter HCPCS Level II codes: A4351, A4352, and A4353	**7 out of 14** (50%)	**4 out of 4** (100%)
Non-Standard Catheter Coverage: Sterile Technique	**3 out of 14** (21%)	**1 out of 4** (25%)
Non-Standard Catheter Coverage: Special Coating (i.e., hydrophilic)	**0 out of 14** (0%)	**2 out of 4** (50%)
Non-Standard Catheter Coverage: Length**	**0 out of 14** (0%)	**0 out of 4** (0%)
Step Therapy	**6 out of 14** (43%)	**1 out of 4** (25%)
Secondary Coding (general)	**7 out of 14** (50%)	**4 out of 4*** (100%)
Secondary Coding: Modifier SC	**0 out of 14** (0%)	**2 out of 4*** (50%)

Coding Element Referenced in Payer Policy*	Commercial Payers (Total assessed: 14)	Public Payers (Total assessed: 4)
Secondary Coding: Modifier U4	**N/A** (Medicaid specific Modifier Code)	**2 out of 4*** (50%)
Secondary Coding: 9943N AT**	**0 out of 14** (0%)	**0 out of 4** (0%)
Secondary Coding: 9993N AT**	**0 out of 14** (0%)	**0 out of 4** (0%)
Secondary Coding: E1399	**3 out of 14*** (21%)	**3 out of 4*** (75%)
Secondary Coding: A4335	**4 out of 14*** (29%)	**4 out of 4*** (100%)
Secondary Coding: 51701	**2 out of 14*** (14%)	**0 out of 4** (0%)
Secondary Coding: Modifier 25** (used in conjunction with CPT code 51701)	**0 out of 4** (0%)	**0 out of 4** (0%)

* Mentioning of coding element in policy does not imply direct application to intermittent urinary catheters or coverage.

** Indicates coding elements that neither commercial nor public payers referenced in their policy.

3.2.1 Existing Intermittent Urinary Catheter HCPCS Level I and Level II Codes

Commercial Payer Takeaway – HCPCS Level II Codes:

- Seven of the 14 commercial payers referenced **existing Intermittent Urinary Catheter HCPCS Level II codes A4351, A4352, and A4353 in their policy.**
    - *Aetna – commercial; Anthem HealthKeepers – Virginia Medicaid; BlueCross BlueShield of North Dakota – commercial and Medicaid Expansion; BlueCross BlueShield of Tennessee – commercial and Medicare Advantage; Humana – Medicare Advantage; Kaiser Permanente – HMO Washington Plan; UnitedHealthcare – Medicare Advantage*
- Furthermore, all seven of those commercial payers referenced all three codes in their policy without exception, i.e., no payer only made references to one or two of the existing codes. **Coverage determinations are made for the entire, existing code set.**

Public Payer Takeaway – HCPCS Level II Codes:

- All four public payers referenced **existing Intermittent Urinary Catheter HCPCS Level II codes A4351, A4352, and A4353 in their policy.**
    - *Texas Medicaid; Michigan Medicaid; Medi-Cal; Veterans Affairs Federal Supply Schedule (VA FSS)*

- Furthermore, all four of these public payers referenced all three codes in their policy without exception, i.e., no payer made references to one or two of the existing codes only. **Coverage determinations are made for the entire, existing code set.**

Note Regarding Existing HCPCS Level I/ CPT Code 51701 and Modifier 25:

- CPT code 51701 is for "Insertion of a non-dwelling bladder catheter."
- Out of a total of 18 payers, only two commercial payers (Cigna – Kansas Cigna Connect/ Marketplace and Kaiser Foundation Health Plan of Washington – commercial) referenced CPT code 51701. However, mentioning of codes in standard charges document does not assume coverage.
    - *Cigna − Kansas Cigna Connect:* Referenced the code in the UNC Health South Eastern. CDM Standard Charges – Cigna.
    - *Kaiser Foundation Health Plan of Washington:* Mentioned the code under Intermittent Catheterization and Supplies. The code was identified in the preauthorization code check search engine on Kaiser Foundation Health Plan of Washington website under the Core Group HMO plan selection. The code is also mentioned in the Authorization Code Ranges − Urology as needing prior authorization to be provided. All services must be considered medically necessary and certain services may be subject to additional clinical review.
- Modifier code 25 – used in conjunction with CPT code 51701, was not referenced in any of the assessed payer policies. Modifier code 25 "Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service" is used when distinct services are performed on the same day.

3.2.2 Non-Standard Catheter Coverage

Commercial Payer Takeaway:

- **Three of the 14** commercial payers referenced **sterile techniques** in their policies.
    - *United Healthcare – Medicare Advantage:* Intermittent catheterization using a sterile intermittent catheter kit (A4353) is covered when the beneficiary requires catheterization, and the beneficiary meets one of the following criteria (1-5):
        - The beneficiary resides in a nursing facility.
        - The beneficiary is immunosuppressed, for example (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
        - 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 (for duration of pregnancy only).
        - 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-month prior to the initiation of sterile intermittent catheter kits.

The sterile intermittent catheter kit (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. The Coding Guidelines section of the related Policy Article has a list of contents of the kit (A4353).

- *Aetna – Commercial:* Intermittent catheterization using sterile technique is considered medically necessary when the member requires catheterization, and the member meets certain criteria. Intermittent catheterization using sterile technique is of no proven benefit for other indications. Requests for sterile intermittent catheterization for members who fail to meet certain criteria are subject to medical review.
- *BlueCross BlueShield of North Dakota – Commercial and Medicaid Expansion*: Intermittent catheterization using sterile technique may be considered medically necessary when the individual requires catheterization, and the individual meets any one (1) of the following criteria:
  - The individual resides in a nursing facility; or
  - The individual is immunosuppressed, for example (not all inclusive):
    - Has a drug-induced state such as chronic oral corticosteroid use; or
    - On a regimen of immunosuppressive drugs post-transplant; or
    - On cancer chemotherapy; or
  - The individual has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization; or
  - The individual is a spinal cord-injured female with neurogenic bladder who is pregnant (for duration of pregnancy only); or
  - The individual has had distinct, recurrent UTI's, while on a program of clean intermittent catheterization with sterile lubricant, twice within the 12-month period prior to the initiation of sterile intermittent catheterization.

  One (1) intermittent catheter with insertion supplies may be considered medically necessary per episode of medically necessary sterile intermittent catheterization. Insertion trays that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and additional component parts may be considered medically necessary only per the stated criteria in each section of this policy.

- **One of the 14** payers referenced **other non-standard catheter coverage**. See more under Step Therapy and Secondary Coding section HCPCS Level II Code E1399.
  - *BlueCross BlueShield of Tennessee – Commercial and Medicare Advantage*: Policy does not detail which non-standard catheters would be covered under the policy but references non-specific code E1399 for primary equipment for which there are not more specific codes available.

- **None** of the commercial payers referenced **special coating** (e.g., hydrophilic)**, or length** in their policies.

Public Payer Takeaway:

- **Two of the four** public payers referenced **special coating** (e.g., hydrophilic) in their policy.
    - *Texas Medicaid:* For hydrophilic catheters, procedure code A4351 must be accompanied with modifier SC.
    - *Michigan Medicaid:* Hydrophilic catheters are considered for individuals that have mitrofanoff stomas, partial stricture, or small, tortuous urethras. Prior authorization is required. There is no unique modifier or code to distinguish hydrophilic catheters from others.
- **One of the four** public payers referenced **sterile techniques, length,** or **other special features** in their policies.
    - *Texas Medicaid*: Sterile incontinence supplies, including supplies in procedure code A4353, are a benefit for clients who are immunosuppressed; have radiologically documented vesico-ureteral reflux; are pregnant and have a neurogenic bladder due to spinal cord injury; or have a history of distinct, recurrent urinary tract infections while on a program of clean intermittent catheterization.

3.2.3 Step Therapy

Commercial Payer Takeaway:

- **Six of the 14** commercial payers referenced **step therapy** in their policy.
    - *Aetna – commercial*: Use of a coudé (curved) tip catheter in female members is rarely medically necessary. A coudé tip catheter is considered medically necessary for either male or female members only when a straight tip catheter cannot be used.
    - *Anthem HealthKeepers − Virginia Medicaid:* For quantities exceeding 180/per month supply. HealthKeepers will only reimburse providers for quantities exceeding Department of Medical Assistance Services (DMAS) limits when prescribed by a physician, documented on a Certificate of Medical Necessity (CMN), and authorized by HealthKeepers. HealthKeepers follows the same criteria as DMAS in determining all medical necessity approval.
    - *BlueCross BlueShield of North Dakota − commercial and Medicaid Expansion*: Intermittent catheterization using sterile technique may be considered medically necessary when the individual requires catheterization, and the individual meets any one (1) of the following criteria:
        - The individual resides in a nursing facility; or
        - The individual is immunosuppressed, for example (not all inclusive):
            - Has a drug-induced state such as chronic oral corticosteroid use; or
            - On a regimen of immunosuppressive drugs post-transplant; or
            - On cancer chemotherapy; or

        - The individual has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization; or
        - The individual is a spinal cord-injured female with neurogenic bladder who is pregnant (for duration of pregnancy only); or
        - The individual has had distinct, recurrent UTI's, while on a program of clean intermittent catheterization with sterile lubricant, twice within the 12-month period prior to the initiation of sterile intermittent catheterization

      One (1) intermittent catheter with insertion supplies may be considered medically necessary per episode of medically necessary sterile intermittent catheterization. Insertion trays that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and additional component parts may be considered medically necessary only per the stated criteria in each section of this policy.
    - *BlueCross BlueShield of Tennessee − commercial and Medicare Advantage:* Unlisted, miscellaneous, non-specific, and NOC codes (e.g., E1399) should only be used when a more specific CPT or HCPCS code isn't available or appropriate. Components of the primary equipment should be billed with the most specific CPT or HCPCS code or the most specific unlisted, miscellaneous code. DME billed with an unlisted, miscellaneous, non-specific, and NOC codes must be billed with the name of the manufacturer, product name, product number and quantity provided. Modifier codes are used for items furnished in conjunction with urological supplies (AU), or prosthetic devices (AV; however, it is unclear if this payer deems urinary catheters prosthetics), as well as DMEPOS items delivered by mail (KL).
    - *Cigna (Kansas Cigna Connect) − Marketplace*: The policy states that consumable medical supplies can be allowed under the lead referral/precertification for the associated services. Cigna considers urinary catheters consumable medical supplies per their medical devices.
    - *UnitedHealthcare − Medicare Advantage*: Use of a coudé (curved) tip catheter (A4352) in female beneficiaries is rarely reasonable and necessary. When a coudé tip catheter is used (either male or female beneficiaries), there must be documentation in the beneficiary's medical record of the medical necessity for that catheter. An example would be the inability to catheterize with a straight tip catheter. This documentation must be available upon request. If documentation is requested and does not substantiate medical necessity, claims will be denied as not reasonable and necessary.

Public Payer Takeaway:

- **One of the four** public payers referenced **step therapy** in their policies.
    - *Texas Medicaid*: See section 3.2.2 Non-Standard Catheter Coverage regarding sterile incontinence supplies.

3.2.4 Secondary Coding

In general, payers that accept and reference secondary codes in their policies include half of the commercial payers (7 of 14) and all public payers (four of four). However, reference of secondary codes may not be related to intermittent urinary catheters and does not imply coverage.

3.2.4.1 Modifier SC

Commercial Payer Takeaway:

- **None** of the commercial payers referenced **modifier code SC** in their policies.

Public Payer Takeaway:

- **Two of the four public payers** referenced **modifier code SC** in their policies. For one payor, the modifier must be used for hydrophilic catheters (A4351), and the other reference is not related to catheters.
    - *Texas Medicaid:* Procedure code A4351 denotes catheters used for intermittent catheterizations. Procedure code A4351 must be accompanied with modifier SC when a hydrophilic catheter is used. For hydrophilic catheters, procedure code A4351 must be accompanied with modifier SC.
    - *Michigan Medicaid:* Examples of non-catheter related use of modifier SC: Waiver agencies must use the SC modifier when billing for ancillary items that are only available for specific medically related travel. This includes meals (A0190, A0210), lodging (A0180, A0200), and waiting time for air ambulances and non-emergency vehicles (T2007).

3.2.4.2 Modifier U4

Commercial Payer Takeaway:

- **None** of the commercial payers referenced **modifier code U4** in their policies as this is a Medicaid specific modifier.

Public Payer Takeaway:

- **Two of the four public payers** referenced **modifier code U4** in their policy. However, these references are not specific to catheters but rather pediatric supply items and other medical supplies.
    - *Michigan Medicaid:* Pediatric Supply Item: Use with HCPCS codes listed on the MDHHS Medical Supplier/DME/Prosthetics and Orthotics Fee Schedule that list the U4 modifier for pediatric pricing only.
    - *Texas Medicaid*: Examples of non-catheter related use of modifier U4: Alcohol wipes (procedure code A4245) and urine test or reagent strips or tablets (procedure code A4250) are a benefit of Texas Medicaid when they are necessary for the treatment of some diabetic conditions or other conditions and therefore are not limited to the diagnoses listed in the diagnosis code table above. Use pump procedure code E0784 with modifier UD and procedure code E2102 with modifier U4 for an insulin pump that has adjunctive CGM capability. Pump

procedure code E0784 with modifier UD and procedure code E2103 with modifier U4 may be used for an insulin pump that has therapeutic CGM capability. B9998 with modifier U4 Standard gastrostomy tube. Long-term pulse oximetry (procedure code E0445 with modifier U4) may be a benefit of Texas Medicaid through the Comprehensive Care Program (CCP) with prior authorization. Claims for a subcutaneous injection port must be submitted with procedure code A4211 and modifier U4.

3.2.4.3 9943N AT

Commercial Payer Takeaway

- **None** of the commercial payers referenced **9943N AT** in their policies.

Public Payer Takeaway

- **None** of the public payers referenced **9943N AT** in their policies.
    - *Note:* AA Homecare stated in their application to CMS that Medi-Cal uses this local code to describe hydrophilic catheters with insertion supplies. However, MITRE could not find any reference (general or specific to Medi-Cal) to this code when conducting the environmental scan.

3.2.4.4 9993N AT

Commercial Payer Takeaway

- **None** of the commercial payers referenced **9993N AT** in their policies.

Public Payer Takeaway

- **None** of the public payers referenced **9993N AT** in their policies.
    - *Note:* AA Homecare stated in their application to CMS that Medi-Cal uses this local code to describe hydrophilic straight catheters. However, MITRE could not find any reference (general or specific to Medi-Cal) to this code when conducting the environmental scan.

3.2.4.5 HCPCS Level II Code E1399

Commercial Payer Takeaway

- **Three of the 14** commercial payers referenced **E1399** in their policies. The references to E1399 are for miscellaneous supplies.
    - *CareFirst Blue Cross BlueShield Federal Employees:* HCPCS code E1399 is included on the list of DME requiring pre-authorization with no additional details provided.
    - *CareFirst Blue Cross BlueShield QHP – Marketplace:* HCPCS code E1399 is included on the list of DME requiring pre-authorization with no additional details provided.
    - *BlueCross BlueShield of Tennessee – commercial and Medicare Advantage*: the policy states that unlisted, miscellaneous, non-specific, and NOC codes (e.g., E1399) should only be used when a more specific CPT or HCPCS code isn't

available of appropriate. DME billed with an unlisted, miscellaneous, non-specific, and NOC codes must be billed with the name of the manufacturer, product name, product number and quantity provided.

Public Payer Takeaway

- **Three of the four** public payers referenced **E1399** in their policies. The references to E1399 are for miscellaneous supplies.
    - *Texas Medicaid:* The policy makes non-catheter specific references. Procedure codes E1399 and A9900 may be reimbursed to DME providers for services rendered in the home setting. […] will be reviewed by a medical director.
    - *Michigan Medicaid:* The policy makes non-catheter specific references. This HCPCS code is used to report repairs or replacements of miscellaneous durable medical equipment, such as a window air-conditioning unit if certain criteria are met.
    - *Veterans Affairs Federal Supply Schedule:* DME is considered medical necessary when the following criteria is met:
        1. Is medically necessary for the treatment of a covered illness or injury.
        2. Improves the function of a malformed, diseased, or injured body part, or delays further deterioration of a patient's physical condition.
        3. Is primarily and customarily used to serve a medical purpose, rather than primarily for transportation, comfort, or convenience.
        4. Provides the medically appropriate level of performance and quality for the medical condition present, that is, non-luxury and non-deluxe.

3.2.4.6 HCPCS Level II Code A4335

Commercial Payer Takeaway

- **Four of the 14** commercial payers referenced **A4335** in their policies in regard to miscellaneous supplies. HCPCS code A4335 is referenced as not covered in one of the commercial payer's policies while another policy references the HCPCS code in a standard charges document that does not guarantee coverage.
    - *Aetna – Commercial:* HCPCS codes not covered for indications listed in the Clinical Policy Bulletins [other than for home care suppliers]: A4335. The following supplies used in the management of incontinence are not covered, other than for home care suppliers who bill for the supplies as part of the home healthcare visit, because they are not prosthetic devices and are not required for the effective use of a prosthetic device: catheter care kits; other incontinence products not directly related to the use of medically necessary urinary catheter or external urinary collection device.
    - *BlueCross BlueShield of North Dakota – Commercial and Medicaid Expansion:* The policy states prosthetic devices dispensed to an individual prior to performance of the procedure that will necessitate use of the device will be denied as non-covered for the treatment of the individual's condition. Catheter kits are listed as an example of a supply use in the management of incontinence that is

non-covered, because they are not prosthetic devices and are not required for the effective use of a prosthetic device.
    - *Cigna (Kansas Cigna Connect) – Marketplace:* HCPCS code A4335 is mentioned in the standard charges document not in a coverage policy. A code referenced in the standard charges document does not guarantee coverage.
    - *Kaiser Permanente – HMO Washington Plan:* HCPCS A4335 code is referenced as covered when considered medically necessary and where certain services may be subjected to additional clinical review criteria.

Public Payer Takeaway

- **All four** public payers referenced **A4335** in their policies but are not specific to catheters.
    - *Texas Medicaid:* Procedure code A4335 is referenced but not specific to catheters, rather it is specified for diaper wipes within the policy.
    - *Michigan Medicaid:* Procedure code A4335 is referenced but not specific to catheters. Instruction on use of this procedure code is only to report belted/unbelted undergarments without sides. Prior authorization is not required up to the established quantity limit of 150 per month.
    - *Medi-Cal:* Procedure code A4335 is referenced but not specific to catheters, rather it is specified for incontinence creams and washes within the policy.
    - *Veterans Affairs Federal Supply Schedule:* Procedure code A4335 is identified in a reasonable charges data table for outpatient and professional services not in a coverage policy. A code referenced in the reasonable charges data table does not guarantee coverage.

3.2.4.7 HCPCS Level I / CPT Code 51701

Commercial Payer Takeaways:

- **Two of the 14** commercial payers referenced HCPCS Level I code **51701**.
    - *Kaiser Permanente – HMO Washington Plan:* This procedure code is referenced in the Authorization Code Ranges − Urology as needing prior authorization to be provided. All services must be considered medically necessary and certain services may be subject to additional clinical review. This procedure code also referenced in the prior authorization code check search under Core Group Plan coverage as needing prior authorization from a provider.
    - *Cigna (Kansas Cigna Connect) – Marketplace:* Procedure code 51701 is referenced pertaining to urinary catheters within UNC Health Southeastern: CDM Standard Charges document.

Public Payer Takeaways:

- **None** of the public payers referenced procedure code **51701** in any of their policies.

3.2.4.8 Modifier 25 (used in conjunction with CPT code 51701)

- **None** of the payers referenced modifier code 25 in conjunction with CPT code **51701** in their policies.

4 Current Ordering, Supplying, and Claims Processing Practices for Intermittent Urinary Catheters

4.1 Assessment of Ordering and Supplying Practices

MITRE consulted two staff clinicians from Michigan Medicine, a highly regarded academic medical center and a CMS five-star rated hospital system affiliated with the University of Michigan Medical School. The clinicians, a board-certified urologist and a nurse educator certified in wound, ostomy, and continence care, responded to a series of questions focused on patient assessment, catheter ordering, and adjustments to orders based on adverse events.

The subsections below summarize key takeaways from the clinician responses. MITRE also performed an unstructured interview with a DME supplier from the perspective of a new patient to ascertain the steps and inputs necessary for the patient to receive catheters from the supplier. Findings from this activity are summarized in section 4.1.2.

Taken together, the input from the clinicians and unstructured interview of the supplier concludes the current coding for intermittent urinary catheters is not adversely impacting the ordering or delivery of catheter supplies to patients. Multiple factors beyond the choice of codes to describe the desired product impact the ordering and delivery fulfillment process. Additional HCPCS Level II codes for catheters, while more descriptive, would generally not ameliorate the issues that clinicians and patients encounter in receiving the desired catheter supplies in a timely fashion.

4.1.1 Clinician Perspective

The selection of a urinary catheter for starting intermittent catheterization should be thought of as a simultaneous assessment of multiple variables consistent with personalized medicine and patient care.

There is no industry-wide consensus on choosing catheters or providing catheterization education, so most clinicians establish their own standards for their practice. Larger health centers, like Michigan Medicine, may invest in assessments connected to the Electronic Health Record (EHR) systems used at the patient visit. MITRE's clinical consultants advise in their system the assessment is multifactorial, covering at least seven assessment areas:

1. Educational needs and support (caregiver assistance)
2. Allergies, specifically to latex
3. Anatomic considerations including sex assignment
4. Body limitations
5. History of UTI
6. Patient preference
7. Insurance coverage for supplies

This thorough patient assessment is documented within the EHR record, and in-office patient education is scheduled to provide the patient with opportunities to fine-tune self-catheterization using a catheter under nurse supervision. Patient education is followed by the catheter ordering process, which is initiated by the prescribing physician and carried out by the DMEPOS supplier.

Supplies are almost always shipped directly to the patient's home, with little interaction between physician and patient after the signed written order is submitted for payment to the patient's insurer.

There are several steps and inputs for the ordering process detailed that complicate the efficient and accurate delivery of the requested urinary catheters. While these steps can frustrate physician office staff and patients, the challenges are related to factors beyond the coding considerations. Physicians can be as specific as necessary in the written order sent to the supplier, and physicians often supplement the order with medical notes and other supporting information to aid in the ordering process. This process is repeated annually for patients as orders are only good for one year.

Patient needs in a urinary catheter may change, as any of the factors listed above can evolve over time and necessitate a reassessment of the patient and require an update to a new catheter prescription. The re-assessment of the patient will focus on the issue impacting the success of self-catheterization, and generally follows the same steps of the initial patient assessment. Revised written orders are sent to the DMEPOS supplier for fulfillment.

Coding is not a barrier to writing an accurate prescription or for revising a prescription for urinary catheters. However, suppliers do have latitude in what is supplied unless the prescribing physician includes a "dispense as written" notation on the written order. Physicians hesitate to take this step since doing may result in increased costs for patients who may not have sufficient insurance to fully cover the cost of the ordered supplies.

4.1.2 Patient Perspective

Patients require instructions on the technique and risks for proper intermittent urinary catheter use. Intermittent catheterization is the standard treatment for patients with chronic urinary retention. There are several complications with intermittent catheterization including UTI, urogenital infection, urethral bleeding, urethritis, urethral stricture, and bladder stones. Timely catheterization to completely empty the bladder and avoid bladder overfilling is the most important technique to prevent UTI. Many patients report that having the ability to self-catheterize provided them with a sense of control over their condition and significantly improved their quality of life. Those who were able to afford hydrophilic catheters reported that the benefits were even more numerous and impactful compared to using regular catheters that required them to apply a lubricating gel.

Patients may face several challenges in the timely and accurate receipt of intermittent catheters as prescribed by their physician according to their unique needs. Challenges such as access to the physician office for in-person learning of proper technique, ability to afford additional catheters beyond the insurer-covered amount, and complexity of the catheterization process may disparately affect some patients more than others, including those in rural areas or with mobility issues affecting efficient travel. While these challenges are distressing and may impact health outcomes for the patient, these issues cannot be addressed directly through additional specificity in the code set for intermittent catheters. To gain insight on the challenges faced by patients who need catheter supplies, MITRE conducted an unstructured interview with a supplier by reaching out to a supplier in the role of a new patient.

MITRE interviewed a randomly selected supplier with the interviewer taking the role of the patient. In this exercise, the patient was a first-time self-catheterization user and requested help from the supplier in navigating the doctor's written order. The supplier explained that if the

order, for example, specified a straight tip catheter, providing insurance details would show the options of straight catheters available to the patient. To help understand how insurance and price may influence the advice from the supplier, the patient expressed concern about cost. The supplier explained that most payers cover most of the options available for straight or curved tip catheters. The supplier also explained that payers were mostly restrictive about the quantity of catheters they will cover per month, and not as restricted about brand or type.

To assess how specific needs are accommodated, the interviewer asked about hydrophilic catheters options for most patients. In response, the supplier explained that most hydrophilic catheters are covered and selection of a hydrophilic catheter mostly depends on the patient's choice. The supplier noted that catheters associated with code A4353 were more restricted in access by insurers according to the supplier. The supplier described the process whereby they request additional doctor's notes to ensure these catheters will be paid for by the insurances, including Medicare and Medicaid. The supplier added that for curved tip catheters the order needs to include justification for this tip type (e.g., patient has strictures in the urethra).

4.1.3 Manufacturer and Supplier Intermittent Catheter Classification Practices

The inventory of six intermittent catheter manufacturers was researched to assess how the catheters are generally classified in their sites (see "Intermittent Catheters Manufacturers List of Products" as noted in Table B.1). Intermittent catheter descriptions follow the HCPCS Level II codes grouping (straight, curved, and closed system). Straight catheters are found grouped by gender, coating, and manufacturing material (e.g., vinyl or PVC, red rubber). Curved catheters are grouped by coating and material. Hydrophilic is the predominant coating available in all the sites. The term pre-lubricated is used in most sites and includes hydrophilic coatings. Hydrophilic catheters are available with or without insertion sleeves. One manufacturer lists only hydrophilic catheters. Another manufacturer does not list coated or pre-lubricated catheters. Pediatric is another grouping; here the predominant catheters are straight uncoated or hydrophilic. Closed systems inventory is diverse, including straight, curved and olive tips, uncoated or pre-lubricated, including hydrophilic coating. In addition to PVC, red rubber catheters are available in this group. Other groupings of catheters available are soft, red rubber, silicone, DEHP free, latex free, and compact catheters. The most common materials used for catheters are vinyl or PVC and red rubber.

MITRE reviewed the inventory of three suppliers to assess how intermittent catheters are described and grouped (see "Intermittent Catheters Suppliers List of Products" in Table B.1). The groupings are similar to the groupings of manufacturers in terms of using the HCPCS Level II codes categories. Suppliers add more searching options including unisex under gender, brand, manufacturer, tip, length, coating, material, style, and number of catheters per unit. Suppliers' coating options include hydrogel, hydrophilic, pre-lubricated, and uncoated. Similar to manufacturers, the term pre-lubricated includes hydrophilic catheters. Hydrophilic is the predominant coating available from suppliers researched. Both manufacturers and suppliers offer a large inventory of sleeve/grip options; most are sleeve/grips included with the catheter (not as a closed system), several are sleeve/grips as part of a closed system, and a few stand-alone grippers are available as insertion aids.

4.2 Assessment of Administrative and Claim Processing Processes

During calendar year 2021, Medicare paid more than $308 million for intermittent urinary catheters. Further, prior reviews by OIG and CMS identified high improper payment rates for intermittent urinary catheters. One of OIG's active workplans is an audit of Medicare payments for intermittent urinary catheters to determine whether claims submitted by DMEPOS suppliers complied with Medicare requirements and guidance.

According to the 2022 Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data, the projected national improper payment rate for the Medicare FFS Program was 7.2 percent. DMEPOS improper payments accounted for 7.0 percent of the national improper payments. Within DMEPOS services, urological supplies were one of the top 20 service types with the highest improper payments rate of 24.9 percent, as noted in Table 4-1,with a projected improper payment amount of over $87 million. Urological supplies improper payments were due to insufficient documentation (64.4 percent), medical necessity (1.5 percent), incorrect coding (9.0 percent), and "other" errors (25.2 percent). In fiscal year 2022, both coudé tip urinary catheters (A4352) and intermittent urinary catheter "kits" (A4353) were identified as having high overpayment rates for DMEPOS services (in the top 20), with overpayment rates of 27.1 percent and 47.0 percent, respectively. It is notable that in 2021, straight tip urine catheter (A4351) was one of the top 20 service-specific overpayment DMEPOS with an overpayment rate of 23.8 percent.

The prevailing LCD does not specifically request additional documentation beyond what is available on the claim form. Noting the high rate of improper payment related to insufficient documentation, it is possible that certain claims paid should have been suspended for further medical review. The higher-cost catheters, such as those having advanced features like no-touch sleeves, special tips, or coatings (which are not currently described by unique HCPCS Level II codes) appear on the claim equivalent to the basic catheters which are less costly. More descriptive codes for these specialized catheters would enable DMEPOS Medicare Administrative Contractors to focus coverage requirements to the conditions for which these catheters are medically necessary, thereby reducing the improper payments for these items.

There is a secondary benefit of more descriptive coding for certain catheters. Specificity in coding permits the ability of automated edits in commercial and public payor claims processing systems. These edits speed the processing time for claims, reduce the cost of adjudicating claims, avoid "pay and chase" scenarios where improper payment must be recouped from the supplier and decrease uncertainty of payment for patients who will likely be balance-billed for catheter costs not covered by insurance.

Table 4-1: 2022 Medicare Fee-for-Service Improper Payment

Improper Payment Category	Urological Supplies	DMEPOS	National
Improper Payment Rate	**24.9**	**25.2**	**7.46**
Insufficient Documentation	64.4	66.2	63.6
Medical Necessity	1.5	6.8	13.8
Incorrect Coding	9.0	0.8	10.5
No Documentation	0.0	11.2	3.8
Other Error	25.2	15.1	8.3