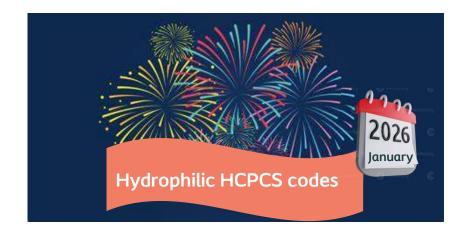
Preparing for upcoming intermittent catheter HCPCS code changes

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Speakers



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Agenda

- 1. New HCPCS codes for hydrophilic coated intermittent catheters
- 2. Medicare coverage criteria
- 3. Benefits of hydrophilic coated intermittent catheters
- 4. Opportunities for DME providers in 2025
- 5. Steps you can take to be prepared
- 6. Payor resources available





New HCPCS codes for hydrophilic coated intermittent catheters





AAHomecare's Intermittent Catheter Coding Reform Coalition (ICCRC) addressed IC HCPCS challenges

- Current IC HCPCS codes do not provide enough differentiation with 1,300 products¹ constrained into 3 HCPCS codes:
 - Negative impact on access to innovative products
 - Negative impact to clinician choice and preference
 - Limited data collection opportunities
 - Leaves DME suppliers vulnerable to dispensing a device not suited to the beneficiaries needs
- A multi-stakeholder coalition led by AAHomecare, focused on protecting access to catheters, applied for new HCPCS codes to recognize various catheter technologies in July 2022
- CMS published a final decision in August 2024, revising current codes and establishing new codes for hydrophilic coated technology, effective January 1, 2026





















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CMS created 3 new and modified 2 HCPCS codes to distinguish hydrophilic coating technology effective January 1, 2026

A4351 Straight tip, with or without coating (teflon, silicone, or hydrophilic, silicone elastomer, etc.), each A4352 Coude tip, with or without coating (teflon, silicone, or hydrophilic, etc.) A4352 Coude tip, with or without coating (teflon, silicone, or hydrophilic, silicone elastomer, etc.), each A4352 Coude tip, with or without coating (teflon, silicone, or hydrophilic, silicone elastomer, etc.), each A4353 Coude tip, with or without coating (teflon, silicone, or hydrophilic, silicone elastomer, etc.), each A4353 Catheter with insertion supplies A4353 - Intermittent catheter with insertion supplies A4353 - Intermittent catheter, hydrophilic coating, with insertion supplies, each





Medicare will either update the existing Urological LCD or publish a new one

- Non-discretionary LCD change
 - Add the new codes to the LCD without changing the clinical indications
 - No changes to the coverage criteria
 - No notice and comment period
- 2. Discretionary LCD change
 - Published proposed LCD to add or modify clinical indication criteria for catheters
 - Notice and comment period will be allowed (45 days)
 - Publication of the final LCD











Intermittent catheters current coverage criteria





Intermittent catheters (ICs) 101:

- Single-use¹ medical device that is inserted through the urethra to drain the bladder 4-6 times daily² (~1,825 per year)
- Covered by Medicare under the "prosthetic device benefit" category
- Utilized by individuals with permanent urinary retention and/or permanent urinary incontinence, including those with neurogenic lower urinary tract dysfunction (NLUTD)
 - Spinal cord injury, spina bifida, multiple sclerosis,
 Parkinson's, late-stage diabetes, stroke, cancer, enlarged prostate (BPH), prolapse⁴
 - Urinary tract infections (UTI) are a major burden for individuals with NLUTD⁵
- Catheter choice is complex and multi-factorial⁶



1. U.S. Food and Drug Administration. Reprocessing of single-use medical devices: Information for health care facilities. Reprocessing Single-Use Medical Devices: Information for Health Care Facilities | FDA
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Medicare Urological Local Coverage Determination and Policy Article

Requirements for coverage of catheters:

- ✓ Diagnosis of permanent urinary incontinence or permanent urinary retention must be present
 - Permanent impairment of urination
 - ✓ Does not mean there is no possibility that the beneficiary's condition may improve in the future
 - ✓ Condition is of long and indefinite duration

Urological Policy Article Update!²

- The updated language removes the specificity of the 3-month requirement of permanence however it does <u>not</u> remove the requirement of permanence
- Language aligns with the Medicare Benefit Policy Manual and the Medicare Program Integrity Manual

Permanent= long and indefinite duration of 3 months or more



Permanent = long and indefinite duration



^{3.} Medicare Benefit Policy Manual (100-2 Chapter 15 Section 120): https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf





^{1.} Urological LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33803&ver=47&bc=0

^{2.} Urological Policy Article: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52521&ver=48

^{4.} Medicare Program Integrity Manual (100-8 Chapter 5): https://www.cms.gov/regulations-and-guidance/quidance/manuals/downloads/pim83c05.pdf

Medical justification for the type of intermittent catheter prescribed must be present in the medical record¹

A4351: Straight intermittent catheter	A4352: Coude intermittent catheter	A4353: Intermittent catheter with insertion supplies (closed or no touch system)
Diagnosis of permanent urinary incontinence or permanent urinary retention	Diagnosis of permanent urinary incontinence or permanent urinary retention	Diagnosis of permanent urinary incontinence or permanent urinary retention
	Medical need for a coude catheter	Beneficiary meets one of the five criteria: 1. Resides in nursing facility 2. Is immunosuppressed, for example (not all-inclusive) • On immunosuppressive drugs post-transplant, • On cancer chemotherapy, • Has AIDS, • Has a drug-induced state like chronic oral corticosteroid use, • High-level spinal cord injury 3. Vesico-ureteral reflux while using IC 4. SCI pregnant female with neurogenic bladder 5. Two UTI's within 12 months • Urine culture greater than 10,000 colony forming units • Presence of one or more symptoms (fever, change in urgency, frequency or incontinence, new or increased autonomic dysreflexia, increased muscle spasms, pyuria, signs of prostatitis, epididymitis, orchitis).
	Reason why a straight IC cannot be used. A diagnosis such as benign prostatic hyperplasia (BPH) alone is not enough. The medical records must document the reason why straight tip catheter is not appropriate.	





To justify payment for intermittent catheters the DME supplier must meet the documentation requirements

Required documentation¹

- Standard written order (SWO)
 - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
 - 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
 - Quantity to be dispensed, if applicable
 - Treating Practitioner Name or NPI
 - Treating practitioner's signature
 - Order date
- Refill request (if supplies are mailed or delivered by supplier)
- Medical records (signed) supporting the type of catheter prescribed
- Proof of delivery

Medical need is established at first shipment. Further documentation of continued medical need is not needed as long as the beneficiary continues to meet the Prosthetic Devices benefit 2





- 1. Urological supplies documentation checklist https://cgsmedicare.com/jc/checklists/int_cath.pdf
- 2. Urological supplies Policy article <u>Article Urological Supplies Policy Article (A52521)</u>

Benefits of hydrophilic coated intermittent catheters





"Hydrophilic catheter is a type of (not same as) pre-lubricated catheter having a polymer coating that binds water to the catheter to make it slippery. The hydrophilic coating on a catheter is intrinsic to the catheter product (i.e., you cannot wipe the coating off)." ¹

Non-Hydrophilic Coated Catheter







Disclaimer: Coloplast performed this blue dye test to demonstrate that the hydrophilic coating remains on the catheter throughout the catheterization process in contrast with non-hydrophilic coated catheter. The test used current (as of Dec 2024) Coloplast hydrophilic and non-hydrophilic coated catheters.





Hydrophilic coated catheters reduce UTI complications, healthcare utilization, and long-term healthcare costs



Compared to uncoated catheter users, hydrophilic coated catheter users experience:

- 22% reduced risk of UTIs¹
- Up to 55%² reduced risk of urethral trauma ³⁻⁸
- Up to 72% reduced risk of urethral strictures³



Hydrophilic catheter users avoid ~18 complications over their lifetime⁹



After experiencing a UTI, **individuals with SCI are 11X more likely** to experience a UTI the following year. Cumulated health care utilization payments over 2 years after injury is 2.48X higher equal to a median estimate of \$15,131*¹⁰

The American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU), have issued guidelines acknowledging the clinical benefits of hydrophilic technology¹¹⁻¹⁵







Opportunities for 2025





Current reimbursement landscape for intermittent catheters

Medicare and some Medicaid reimbursement for ICs increased since 2021

Medicare

- 2025 Medicare CPIU increase 2.4%¹
- 2024 Medicare CPIU increase 2.6%²
- 2023 Medicare CPIU increase 8.7%³
- 2022 Medicare CPIU increase 5.1%⁴
- 2021 Medicare CPIU Increase 0.2%

Net Increase of 19%

Medicaid

- Some Medicaid rates are a % of Medicare DME fee schedule
- Many Managed Medicaid fee schedules are tied to the state Medicaid rates, which are based on Medicare DME fee schedule
- Medicaid plans not tied to Medicare have been receptive to efforts and have increased low reimbursement rates

^{*} Average Medicare Rates 2025 and Medicaid average calculated from most recent fee schedules available online

^{1. 2025} CPIU – MLN Matters Number: MM13888 (Release Date: December 13, 2024. Effective Date: January 1, 2025) https://www.cms.gov/files/document/mm13888-cy-2025-update-dmepos-fee-schedule-pdf

^{2. 2024} CPIU- MLN Matters Number: MM13463 (Release Date: December 7, 2023. Effective Date: January 1, 2024) https://www.cms.gov/files/document/mm13463-dmepos-fee-schedule-cy-2024-update.pdf 3. 2023 CPIU- MLN Matters Number: MM13006 (Release Date: December 2, 2022. Effective Date: January 1, 2023) https://www.cms.gov/files/document/mm13006-dmepos-fee-schedule-cy-2023-update.pdf

^{4. 2022} CPIU- MLN Matters Number: MM12521 (Release Date: December 2, 2021. Effective Date: January 1, 2022) https://www.cms.gov/files/document/mm12521-calendar-year-2022-update-durable-medical-equipment-prosthetics-orthotics-and-supplies.pdf 5. 2021 CPIU- MLN Matters Number: MM12063 (Release Date: December 4, 2020, Effective Date: January 1, 2021). https://www.cms.gov/files/document/mm12063.pdf

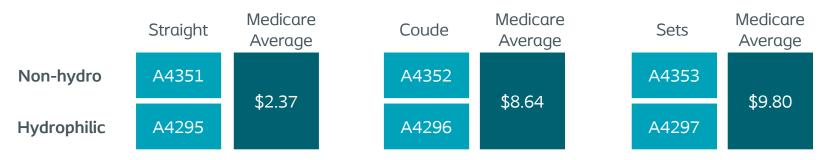
CMS is bound by continuity of pricing regulation, therefore Medicare reimbursement rates for new codes are cross-walked



Regulatory requirement prohibits CMS from changing reimbursement rates for the new codes

§ 414.236 (b) 'Continuity of pricing when HCPCS codes are divided or combined'

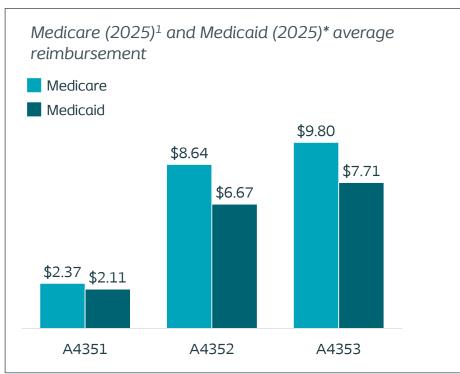
"When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes."

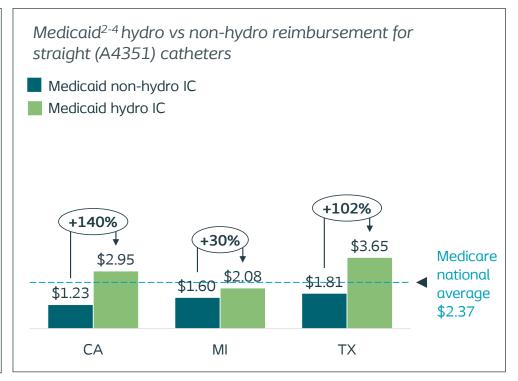






Precedent for higher reimbursement exists with Medicaid for hydrophilic catheters, recognizing hydrophilic benefits





^{3.} Michigan Department of Health and Human Services. (September 2024). Medical suppliers, orthotists, prosthetists, and DME dealers: Billing and reimbursement. https://www.michigan.gov/mdhhs/doing-business/providers/providers/ billingreimbursement/medical-suppliers-orthotists-prosthetists-dme-dealers







^{*} State Medicaid average was calculated from DME fee schedules available online

^{1.} Centers for Medicare & Medicaid Services, (2025), DMEPOS Medicare fee schedule, Retrieved from https://www.cms.gov/medicare/payment/fee-schedules/dmepos/dmepos-fee-schedule

^{2.} California Department of Health Care Services. (October 2024). Durable medical equipment and medical supplies manual. https://mcweb.apps.prd.cammis.medical-equipment-and-medical-equipment-and-medical-supplies.

Action is required to implement new codes with payors and to secure supportive reimbursement with commercial payors

- Implement new HCPCS codes with payors to avoid disruption to patient access
 - Ensure ongoing access to medically necessary hydrophilic coated ICs
 - Support access for members with multiple health plans or have Medicare as primary
 - Reduce financial and administrative burden for cross-over claims
- Obtain supportive reimbursement for hydrophilic catheters
 - Review contracts and current reimbursement rates
 - Discuss 'Carve-Out opportunities' for A4295, A4296 and A4297

Requests prior to 1/1/2026:

- ✓ Implement 3 new HCPCS codes (A4295, A4296, A4297)
- ✓ Revise the definitions of A4351 and A4352 (remove hydrophilic)
- ✓ Assign adequate reimbursement to ensure access to hydrophilic coated intermittent catheters





Steps to take to be prepared





The Pricing, Data Analysis and Coding (PDAC) contractor created a Hydrophilic Intermittent Urinary Catheter Crosswalk¹

- Manufacturers had to establish a primary point of contact (POC) with the PDAC by March 31, 2025
 - Throughout 2025 PDAC is assessing whether existing products qualify for hydrophilic HCPCS codes
 - Crosswalk of products is available on the <u>PDAC's website</u>
- For <u>new products</u> manufacturers need to submit their applications to PDAC before October 31, 2025, to have the products listed on January 1, 2026
 - Applications received after October 31, 2025, will have codes assigned after January 1, 2026.



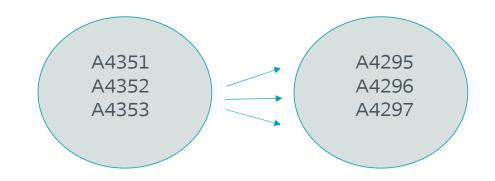




PDAC updated the hydrophilic catheter listing on 6/25/25

The crosswalk is located on the bottom of the website

- Includes 26 pages of information
 - Manufacturer
 - Product Name
 - Model Number
 - Current HCPCS Code
 - Effective Begin Date
 - HCPCS Code (Effective 1/1/26)



<u>Hydrophilic Intermittent Urinary Catheter Crosswalk</u> - updated 6/25/2025





Proactively obtain new Standard Written Order

Medicare SWO requirements:

General description of the item, HCPCS code, HCPCS code narrative, or a brand name/model number) Update order templates

Remove the HCPCS code and replace it with the description of the IC:

- 1. IC type: straight, coude, or closed system
- 2. Coating type: "hydrophilic" or "non-hydrophilic."

Updating the description and removing the HCPCS code could eliminate the need for new written order on or after January 01, 2026. Start NOW!





Additional recommendations

- Proactively communicate to your payors
- Monitor payor(s) fee schedule for early adoption
 - Some update 2026 fee schedule in Q4 2025
- Not all payors may adopt the new codes on January 01, 2026, therefore, update price tables or price files accordingly to avoid rejections/denials
 - Check with your software vendor
- Monitor secondary claims to Medicare as claims may cross over and the payor may not recognize the new code
 - January is deductible season
 - Manual cross-walking of the claims may be required until full adoption
 - Claims may pay based on coordination of benefit(s)
- Educate patients on the new code changes
 - Avoid confusion with explanation of benefits (EOB)







Resources





ICCRC payor resources for DME providers

- Payor brief
- Payor value prop
- Society support letter
- Catheter diagram
- Urological whitepaper
- Infographic on cost increase
- Link to PDAC crosswalk









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Q & A



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~The recording of the webinar will be posted on Coloplast and ACU-Serve websites~



