PureWick™ Urine Collection System and External Urine Incontinence Suction Pumps

Medicare Advantage Medical Policy #MA-235
Original Effective Date: 11/01/2026
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider PureWick™ external catheter to be **eligible for coverage**** when **ALL OF** the following criteria are met:

- Adult patient with documented chronic urinary incontinence; **AND**
- Patient is bed-confined, wheelchair dependent, or non-ambulatory; **AND**
- PureWick™ is requested as an alternative to an indwelling urinary catheter.

Note:
Initial Authorization: *Coverage of PureWick™ external catheters is limited to* ***35 wicks/catheters per month for 6 months****.*

Reauthorization: *Coverage may be extended for an additional* ***6 months*** *when clinical criteria above are met. Documentation must be submitted at the time of reauthorization review. Continued coverage may be considered when medical records support ongoing need for skin protection and/or wound management.*

Note:
HCPCS code E2001 (suction pump for external urine and/or fecal management system) is classified by Medicare as a capped rental DME item and is billed with modifier RR (rental). Medicare's DME replacement policy generally recognizes a reasonable useful lifetime (RUL) of at least five years. Replacement due to ordinary wear typically occurs after the item has reached its RUL, while replacement before the RUL may be covered when the equipment is lost, stolen, irreparably damaged, destroyed, or otherwise meets Medicare replacement criteria.

When Services Are Not Covered

Based on review of available data, the Health Plan considers the use of PureWick™ external catheter to be not covered for ANY OF the following indications:

- Convenience of the patient, caregiver, or healthcare provider.
- Reduction in the utilization of diapers, pads, briefs, or other absorbent products.
- Prevention or reduction of bed linen changes.
- Use solely for custodial care, hygiene management, or maintenance purposes.

Background/Overview

An external urine collection system is a non-invasive urinary management device that collects urine externally rather than through urethral catheterization. These systems are intended to:

- Manage urinary incontinence
- Measure urine output
- Help maintain skin integrity
- Reduce exposure to moisture-associated skin damage
- Potentially decrease the need for indwelling Foley catheters and associated catheter-associated urinary tract infection (CAUTI) risk

PureWick™ is a type of external urine collection system (EUCS) designed to manage urinary incontinence without inserting a catheter into the bladder. It is used primarily in patients with female anatomy and works by placing a soft, external wicking device between the labia and gluteal area. The device is connected to low continuous suction, which draws urine away from the skin into a collection canister.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The PureWick™ Female External Catheter and PureWick™ Flex Female External Catheter are FDA-cleared external urinary management devices intended for non-invasive urine output management in adult patients with female anatomy. These devices are legally marketed in the United States and are regulated by the FDA as Class I medical devices under product code NZU.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Female external urinary management systems are intended to reduce the risk of indwelling catheter-associated urinary tract infections (CAUTIs), and skin irritation associated with incontinence pads

and diapers. Despite its unique design, studies are conflicting regarding the efficacy of these devices to lower CAUTI's, further research is needed to demonstrate the superior nature of these devices.

Prolonged urinary exposure is a recognized contributor to moisture-associated skin damage, incontinence-associated dermatitis, pressure injury progression, and delayed wound healing. Evidence supporting these systems is limited and consists primarily of observational and quality-improvement studies; however, available data suggest that external urinary collection devices may reduce urine exposure and support preservation of skin integrity in selected patients.

Baxter et al. (2025) conducted a randomized, prospective, multi-center, quality improvement study to evaluate the incidence of skin-related complications attributable to incontinence-associated dermatitis (IAD) from the use of an external female urinary catheter device used for urinary incontinence. Participants were randomized to receive one of two commercially available external female urinary catheter devices [catheter A (n = 158) and catheter B (n = 205)]. Median catheter duration was three days in both groups, and the number of catheters used was two in the catheter A group and three in the catheter B group. The authors reported that the frequency of new or worsening skin breakdown was 19 (4.9%) in the Intention to Treat analysis, 19 (5.1%) in the As Treated analysis, and 14 (4.1%) events in the Per Protocol analysis. According to the authors, both devices were associated with an overall low risk (5%) of new or worsening skin breakdown. Regarding the adverse events reported on 15 participants, seven arrived with baseline skin intact and subsequently developed new skin breakdown mostly in the buttocks region, five participants arrived with baseline IAD primarily in the buttocks region that worsened or spread to new skin regions and three participants arrived with baseline coccyx pressure injuries that became worse. Limitations of the study included the inclusion of only hospital units that agreed to participate, the honor system adherence for the randomized allocation, the inclusion of women who could cooperate with care, and the homogenous participant population. The authors concluded that external urinary catheter use in hospitalized female patients with urinary incontinence was associated with low risk of new or worsening overall skin breakdown.

Pryor et al. (2024) conducted a systematic review and meta-analysis to assess the clinical risks and benefits of female external urine wicking devices (FEUWDs) as alternatives to indwelling urinary catheters (IUCs). The systematic review included 50 non-randomized intervention studies, of which 49 were based in the United States. Fourteen of these studies provided sufficient methodological information and interventional in design to be evaluated for quality, of which seven provided adequate outcomes data required for inclusion in meta-analyses; however, all seven demonstrated a moderate or serious risk of bias overall. The authors reported that IUC utilization rates decreased 14% following FEUWD implementation and indwelling CAUTI rates decreased (non-significantly) up to 32%, while the incidence rate of indwelling CAUTIs decreased significantly up to 54% when the authors limited their review to only studies that described protocols for implementation. The authors concluded that FEUWDs non-significantly reduced indwelling CAUTI rates overall, though the reductions were significant among studies describing FEUWD implementation protocols. The authors recommended that standard definitions be developed for consistent reporting of non-

dwelling CAUTI complications such as FEUWD associated UTIs, skin injuries, and mobility-related complications. Limitations of the study include the heterogeneity of the studies involved, the lack of randomization and controls in the studies, the low number of available studies for the meta analyses, the moderate to serious risk of bias in all the studies, the introduction of FEUWDs alongside existing interventions focusing on reducing CAUTIs, and the lack of accountability for confounding interventions. This systematic review included the Beeson, et al. (2023), Eckert et al. (2020), Lem, et al. (2022), Jasperse, et al. (2022), Warren, et al. (2021) and Zavodnick, et al. (2020) studies summarized below.

Beeson et al. (2023) conducted a prospective, observational, quasi-experimental study to examine the effectiveness of an external female urinary management system [external urinary device for female anatomy (EUDFA)] in critically ill women unable to self-toilet and to identify rates of indwelling catheter use, catheter-associated urinary tract infections (CAUTIs), urinary incontinence (UI), and incontinence-associated dermatitis (IAD) before and after the introduction of the EUDFA. The sample included 50 adult female patients in 4 critical/progressive care units using an EUDFA at a large academic hospital in the Midwestern United States. Indwelling urinary catheter use was significantly lower in 2018 (40.6%) and 2019 (36.6%) compared with 2016 (43.9%) ($p < .01$). The rate of CAUTIs was lower in 2019 than in 2016, but not significantly (1.34 per 1000 catheter-days vs 0.50, $p = .08$). The percentage of incontinent patients with IAD was 69.2% in 2016 and 39.5% in 2018-2019 ($p = .06$). The authors concluded that EUDFA was effective in diverting urine from critically ill female incontinent patients and indwelling catheter utilization. This study was limited by impacts of the COVID-19 pandemic, which interrupted and complicated patient enrollment and imposed significant burdens on staff. Additionally, data on IAD prevalence reflect only a single month in each observation year. Finally, the study time frame coincided with a period when the quality focus was on decreasing use of indwelling catheters and implementing a nurse driven internal urinary catheter removal protocol. While the use of an effective EUDFA played a pivotal role in these initiatives, not all reductions in indwelling catheter use or CAUTIs can be attributed to the EUDFA. Further research with randomized controlled trials is needed to validate these findings.

Jasperse et al. (2022) reviewed the records of 848 adult female patients in a retrospective, single center cohort study to compare the catheter associated urinary tract infection (CAUTI) rate and the number of indwelling urinary catheter (IUC) days before and after the PureWick® external urinary collection device (EUCD) was introduced in the internal medicine, family medicine, and neurology units of their facility, Limitations include the retrospective, single-center design, missing data, inconsistencies in charting, potential for reporting bias, the increase in the number of urine cultures ordered in the POST cohort, the lack of a procedure protocol which left the application to provider discretion and the small number of patients included in the study. The authors concluded that, while EUCDs appear to be a promising alternative to IUCs for female patients, their study found that both the median number of IUC days and the CAUTI rate increased after introduction of the PureWick EUCD.

Lem et al. (2022) conducted a retrospective study to compare CAUTI rate and the median number of days an indwelling urethral catheter (IUC) was used before and after availability of this female external urinary catheter device (EUCD) for surgical patients. This retrospective analysis consisted of adult female surgical patients admitted to a single academic institution who received an IUC and/or EUCD was performed. The authors concluded while EUCDs appear to be a promising alternative to IUCs for female surgical patients, this study found increased CAUTIs after introduction of an EUCD. Further research is needed to clarify if female EUCDs are effective in decreasing CAUTI prior to widespread adoption. This may be related to selection bias, with EUCDs being ordered for patients who would not have otherwise received any urinary collection device. The dermatologic injury from the pressure and stiffness of the device also should be taken into account when considering using an EUCD. This study suggests that future prospective randomized controlled trials with explicit indications for EUCD usage are needed to validate these findings.

Warren et al. (2021) conducted a retrospective study analyzing the impact of a hospital-wide implementation of an external female urinary catheter. The investigators compared a 12-month period before and after device implementation to assess the impact on indwelling urinary catheter utilization and CAUTI rate. The study included female patients with a combined patient stay of 220,000 days,10,000 external urinary catheter days and 33,000 indwelling urinary catheter days. The authors concluded that an increase in external female urinary catheter utilization coincided with a decline in patient CAUTI rate, but only in intensive care units (ICUs). Limitations of this study included lack of documentation regarding the catheter type used by the patients and lack of direct correlation of CAUTI decline with use of FEUCs, especially outside of the ICU setting. Further studies are needed to correlate usage of FEUCs versus indwelling catheters (IDCs) and the impact on the CAUTI rate.

Zavodnick et al. (2020) conducted a retrospective, observational study that included nine adult ICUs to investigate CAUTIs rates in adult females. The study compared the use of FEUCs versus IDCs. The authors concluded that FEUCs are associated with a significant decrease in the CAUTI rate among female intensive care participant, and they may prevent the need for indwelling catheters. Further studies are needed with a larger sample-size along with equal usage of both FEUCs and IDCs over the same number of patient days of stay.

Eckert et al. (2020) conducted a quality improvement, single center study comparing the use of an FEUC device with wall suction as an alternative to IDC. The authors concluded they need to continue to prioritize the use of FEUCs over IDCS. Limitations of this study include lack of consistent sample size, short follow-up and lack of equal comparisons of FEUC and IDC patient usage.

Male external urine management systems are intended to reduce the risk of indwelling catheter-associated urinary tract infections (CAUTIs), and skin irritation associated with incontinence pads and diapers. The systems consist of a wicking fabric that is placed over the male urinary anatomy and is connected to continuous low suction to divert urine into a collection vessel. Currently, there

is minimal published clinical evidence and additional published studies are needed to demonstrate the safety and efficacy of using these systems.

Wagg et al. (2024) conducted a prospective, single-blind, comparative, crossover study to assess the efficacy of urine collection using external urine collection devices over two voids in a group of healthy male volunteers. The study included 59 men (mean age 40.8 years old) who were continent and consented to participate in the study. Each participant was randomized to use each device for a single void. The proportion of urine captured by each device was calculated and compared and the results were compared between participants who were morbidly obese (body mass index ≥ 40 kg/m2) and non- morbidly obese (body mass index < 40 kg/m2). The authors reported that for the first void (void 1), the mean proportion of urine captured for Device A (PureWick™ Male External Catheter) was 97.8%, while the mean proportion of urine captured with Device B (Sage PrimoFit™ Male External Catheter) was 90.7%. For void 2, the authors reported that the mean proportion of urine capture for Device A was 91.1% and, for Device B, it was 85.2% with a mean difference between devices of 6.6%. When results were stratified by weight, the authors reported that Device A captured 99.7% and that Device B captured 83.5% of the first void in men who were morbidly obese, while the second voids showed that Device A captured 80.8% versus 79.3% for Device B. The authors concluded that Device A performed significantly better than Device B in capture rates when compared based on voided volume, order of void, or BMI category and that Device A male external catheter system was an effective option for urine management in men who were obese and in men who were not obese. Limitations of the study included the small sample size, and single center design.

Supplemental Information

CGS Medicare Local Coverage Determination (LCD) L33803, Urological Supplies, provides that male external catheters (condom-type) and female external urinary collection devices are considered medically necessary for members with permanent urinary incontinence when used as an alternative to an indwelling urinary catheter. Utilization of male external catheters (HCPCS A4349) is generally limited to 35 catheters per month; requests for quantities exceeding this limit must be supported by documentation demonstrating medical necessity. Male external catheters and female external urinary collection devices are not considered medically necessary when used concurrently with an indwelling urinary catheter. Specialty male external catheters (HCPCS A4326), including inflatable devices, faceplate systems, and extended-wear catheter systems, are covered only when the medical record substantiates the clinical need for the specialty device. For female external urinary collection devices, utilization is generally limited to one meatal cup (A4327) per week, one urinary collection pouch (A4328) per day, or one Tibbe Female External Urinary Device (A4318) per day. Quantities exceeding these limits require medical record documentation supporting medical necessity.

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Policy History

Original Effective Date: 11/01/2026
Current Effective Date: 11/01/2026
08/18/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	A6590, A7001, A7002, E2001
ICD-10 Diagnosis	All related diagnoses

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.