

Developing an Advanced Alternative Payment Model for Stress Urinary Incontinence

Developed by the AUGS Payment Reform Committee

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Abstract: Historically, our health care system has been based on a fee-for-service model, which has resulted in high-cost and fragmented care. The Center for Medicare & Medicaid Services is moving toward a paradigm in which health care providers are incentivized to provide cost-effective, coordinated, value-based care in an effort to control costs and ensure high-quality care for all patients. In 2015, the Medicare Access and Children's Health Insurance Program Reauthorization Act repealed the Sustainable Growth Rate and the fee-for-service model, replacing them with a 2-track system: Merit-based Incentive Payment System and the advanced Alternative Payment Model (aAPM) system. In 2016, the American Urogynecologic Society Payment Reform Committee was created and tasked with developing aAPMs for pelvic floor disorders. The purpose of this article is to describe the stress urinary incontinence aAPM framework, the data selected and associated data plan, and some of the challenges considered and encountered during the aAPM development.

Key Words: alternative payment models, advanced Alternative Payment Model (aAPM), Merit-based Incentive Programs (MIPS), payment reform, episode of care, care pathways, quality measures, stress urinary incontinence

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Historically, our health care system has been based on a hospital- and clinician-centered fee-for-service model with incentives for volume. Although this system has afforded clinicians a great deal of autonomy, it has resulted in high-cost and fragmented care. To control costs and ensure high-quality care for all patients, the Center for Medicare & Medicaid Services (CMS) is moving toward a more patient-centered and sustainable paradigm in which health care providers are incentivized to provide cost-effective, coordinated, value-based care. To this end, the Medicare Access and Children's Health Insurance Program

Reauthorization Act was signed on April 16, 2015. The act repealed the Sustainable Growth Rate and the fee-for-service model and replaced them with a 2-track system. First, in the Merit-based Incentive Payment System (MIPS), health care providers report performance data in four areas: (1) Quality, (2) Improvement Activities, (3) Promoting Interoperability, and (4) Cost. Health care providers are then rewarded (receive higher reimbursements) for meeting benchmarks and penalized (receive lower reimbursements) for failing to meet benchmarks. Second, in the advanced Alternative Payment Model (aAPM) system, a specialist or subspecialist organization develops a model that incorporates all aspects of treating patients with a particular clinical condition, including relevant treatments or procedures, costs for services, and anticipated quality outcomes. Once an aAPM is approved by the CMS, a clinician or practice committed to follow it will receive higher or lower reimbursement according to whether they meet the aAPM metrics of providing high-quality and cost-efficient care.

Recognizing that the aAPM will be an important mechanism by which our members ensure they are appropriately reimbursed for providing high-quality and cost-efficient care, the American Urogynecologic Society (AUGS) Executive Board created a Payment Reform Committee (PRC) in 2016 and tasked it with developing aAPMs for pelvic floor disorders. The PRC was initially charged to focus on an aAPM for stress urinary incontinence (SUI) for several reasons. First, SUI is a common diagnosis, affecting approximately 25%–50% of women.^{1–3} Second, SUI treatment costs up to \$12 billion annually in the United States.⁴ Third, of all of the pelvic floor disorders AUGS members treat, SUI is theoretically the least complex, so an aAPM for SUI should be a good starting point for aAPMs for more complex pelvic floor disorders such as pelvic organ prolapse. Finally, women with SUI are treated by a diversity of health care providers (eg, primary care physicians, general gynecologists, urologists, and female pelvic medicine and reconstructive surgery (FPMRS) specialists) and have numerous treatment options (including but not limited to behavioral modification, pelvic floor physical therapy, continence pessary use, and surgical intervention with urethral bulking, synthetic midurethral sling or urethropexy). Thus, an aAPM that is acceptable to multiple health care provider groups and encompasses numerous treatment strategies should serve as a model for APMs for other pelvic floor disorders.

To accomplish this task, the PRC began meeting in September 2016 in collaboration with the Washington University in St. Louis Center for Advanced Database Research, which has access to CMS administrative claims data. Additionally, an independent consultant and representatives from the American College of Surgeons and the Society of Gynecologic Oncologists who have created APMs in their specialties are also a part of this initiative.

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The purpose of this article is to describe the SUI aAPM framework, the data selected and associated data plan, and some of the challenges considered and encountered during the aAPM development. Once an SUI aAPM is completed, the PRC will seek the opinions of AUGS members because they are likely to have valuable comments and suggestions in an effort to accomplish this important task.

POTENTIAL CHALLENGES

The goal of the aAPM is to help clinicians provide value-based care for their patients with SUI. Specifically, the aAPM should lead to improvements in outcomes by promoting adherence to evidence-based pathways, maintain or improve safety and effectiveness, and reduce the costs of delivering care. In treating SUI and tracking costs and outcomes, the PRC recognized several challenges. First, patients with SUI are treated by surgeons, nurses, physical therapists, and advanced practice nurses. Second, treatment can occur in both ambulatory and hospital settings, each with separate billing mechanisms. Third, subspecialists and ancillary services have not historically been included in joint or shared payment models or risk-adjusted payment structures. Fourth, outcome measures are not standardized, routinely assessed, or benchmarked. Moreover, the majority of outcome measures were developed in the context of clinical trials and, thus, may not be directly applicable to standard, real-world practice. Finally, true estimates of costs for treating SUI are difficult to ascertain from the U.S. medical/insurance system. Our proposed framework attempts to address all of these challenges.

CARE PATHWAY FOR TREATING WOMEN WITH SIMPLE STRESS URINARY INCONTINENCE

The first step of the AUGS PRC was to define the time frame of the care model for treating SUI. Care, associated costs, and quality outcomes were categorized into the following phases (see Table 1): nonsurgical or preoperative care, surgical management, postoperative care, and continuing care. In each phase, care should follow evidence-based practices and pathways that incorporate quality metrics and risk adjustments, and each treatment will have a standardized payment rate.

Nonsurgical or Preoperative Care

The nonsurgical or preoperative phase of care begins with SUI diagnosis and ends at surgery. During this period, the patient will undergo evaluation and management (E&M), appropriate diagnostic testing, and counseling on the range of treatment options, including nonsurgical and surgical treatment modalities. Services provided include office history and physical examination (including assessment of pelvic organ support and demonstration of urine leakage), laboratory testing, and formal bladder testing when appropriate. Critical elements and incurred costs in this phase include appropriate diagnosis (exclusion of other forms of urinary incontinence [UI], specifically mixed and urgency UI); diagnostic

testing, including simple office cystometrics or multichannel urodynamics and cystoscopy when indicated. If the patient chooses nonsurgical therapies, costs could include continence pessary and pelvic floor physical therapy. If the patient chooses surgery, this phase will include evaluation in preparation for surgery (or office procedure, ie, urethral bulking).

Surgical Management

The surgical management phase of care begins with services provided on date of surgery until the date of discharge from the hospital or surgical center. It is anticipated that this phase will include the most intensive use of resources and represent the highest cost. Costs and services include the physician (surgeon, anesthesiologist), hospital procedures, the surgical stay, ancillary health care providers, laboratory costs, equipment, medication, and other associated costs. Critical costs in this phase include selection of surgical approach, including capital cost of implant (sling), open or laparoscopic urethropexy, extent of surgery, and immediate perioperative complications. Anesthesia costs will likely vary depending on length of procedure, choice of surgical route, and anesthesia type (ie, regional or general). Risk adjustment is needed to address potential costs related to patient comorbidities.

Postoperative Care

The postoperative care phase extends from discharge from the hospital or surgical center to 90 days postoperative. Potential high-impact services and costs during this period include acute care visits in ambulatory urgent care clinics or hospital emergency department, laboratory and imaging studies at either type of facility, reoperation for complications related to the anti-incontinence procedure, and supportive services, including nursing calls and visits. For most patients, this phase will require minimal personal financial costs as these should be covered by the global surgical fee. A subset of patients may require substantial use of resources. Included in this group are those who experience surgical complications requiring reoperation for issues such as urinary retention, bleeding, or other procedure-related injury (eg, sling revision or removal, mesh complication). These patients will likely also incur significant costs for emergency department visits, urgent care visits, and follow-up office visits. Identifying risk factors that increase the likelihood of these adverse outcomes is critical to establishing an aAPM that appropriately considers factors that cause some patients to require more resources than others. Alternatively, any efforts to manage these issues in the office or via telephone as opposed to hospital emergency departments and urgent care centers can help to limit increased costs in this phase.

Continuing Care

Although the continuing care phase could arguably last from 90 days postoperative through a woman’s lifetime, we recommend that this phase last 365 days. The continuing care phase will be the most variable in regard to resource utilization and costs because

TABLE 1. Stress Urinary Incontinence Pathway

| Preoperative Care | Surgery | Postoperative Care | Continuing Care |
|------------------------|--------------------|--------------------|-------------------------------|
| Specialist E/M | Sling procedure | Complications | Recurrence evaluation |
| Laboratory | Sling capital cost | ED visits | Recurrence diagnostic testing |
| Diagnostic testing | Ancillary services | Laboratory | |
| Conservative therapies | | | |

Abbreviation: ED, emergency department.

SUI can recur in up to 15% of patients, and urgency UI can coexist in up to 30% of patients and often requires continued care.⁵ This phase also includes any additional diagnostic and/or treatment for women who experience new-onset or worsening urgency UI, new-onset urinary tract infections, SUI recurrence requiring further intervention, and long-term complications, including mesh complications.

Approach to Estimating the Cost of Care for Stress Urinary Incontinence

Ideally, an aAPM for SUI would be based on data from both commercial and Medicare payers so that a single aAPM could be tested for its utility for both payer types and so that different aAPMs could be created for specific payer types. However, because commercial administrative data sets are costly, and a significant proportion of female Medicare beneficiaries (approximately 37%) have SUI, the PRC elected to first develop and test the aAPM on CMS data.⁶ To do so, cost estimates will be obtained from Medicare administrative claims data through the Center for Administrative Data Research. By using administrative claims data, the aims are to (1) define the variability of current practice trends and actual services as well as their related charges for evaluating and managing SUI across the United States; (2) potentially identify services or tests that are overused and thus increase costs; (3) compare “actual practice” trends to existing guidelines or practice recommendations (when available) to identify potential areas of improvement and unmet needs; and (4) identify potential cost savings by determining whether nonadherence to recommended or evidence-based practices (eg, performing unnecessary or unindicated tests or services) increases costs of SUI treatment.

In the analysis of Medicare data, point estimates will be made of all aspects of SUI care, with a description of central tendency, range, and other factors. For example, estimates of the numbers

of E&M visits, office tests (eg, urinalysis, urine cultures), office procedures (eg, cystoscopy, multi-channel urodynamics), imaging studies (eg, ultrasonography, magnetic resonance imaging, computed tomography (CT)), and surgical procedures (eg, midurethral slings, urethral bulking agents, pubovaginal slings, pelvic organ prolapse procedures) will be made. Essentially, all associated out-patient and inpatient claims related to treating SUI will be examined. For each, the associated initial costs for evaluation and treatment as well as costs from visits related to follow-up, complications and retreatments for complications, or persistent/recurrent SUI will be estimated. Only E&M visits, tests, and procedures associated with a diagnosis code for SUI will be included in the analysis to avoid costs associated with other diagnoses that may be made and need evaluation during the evaluation for SUI (ie, cystoscopy and computed tomography (CT) scan urogram for microscopic hematuria).

Once these point estimates are generated, they will be used as “nodes” in decision analysis and cost-effectiveness analysis modeling to project changes in costs if utilization patterns are changed. For example, literature and claims data will be used to project the economic and quality impact if testing not supported by evidence is eliminated. The expected cost reductions of a bundled payment that incentivizes health care providers to forgo lower yield or evaluation not supported by evidence-based recommendations will be modeled. The main outcome of the decision analysis and cost-effectiveness analysis models will be the model “arm” that has the highest success rate (defined as lowest rates of retreatment and complications) with the lowest cost; this will include all costs related to evaluating and treating SUI from initiation of the episode until conclusion of the treatment window.

QUALITY MEASURES AND REPORTING

In an aAPM, improving quality of care is just as important as reducing cost. For example, in MIPS APMs, the composite

TABLE 2. AUGS Quality Measures

| AUGS Measure ID | Measure Title | Measure Definition | NQF Domain | Measure Type |
|-----------------|---|--|---|--------------|
| AUGS 17 | Documentation of weight loss counseling before incontinence surgery for obese women | Percentage of obese patients having documented weight loss counseling before undergoing anti-incontinence surgery. | | |
| AUGS 20 | Patient-Centered Surgical Risk Assessment and Communication | Percentage of patients who underwent nonemergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon. | Person and Caregiver Centered Experience and Outcomes | Process |
| AUGS 23 | Perioperative Care: Selection of Prophylactic Antibiotic –First OR Second Generation Cephalosporin | Percentage of surgical patients 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis. | Patient Safety | Process |
| AUGS 24 | Perioperative Care: Discontinuation of Prophylactic 022 0271 Parenteral Antibiotics (noncardiac procedures) | Percentage of noncardiac surgical patients 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time. | Patient Safety | Process |

Abbreviation: NQF, National Quality Forum.

quality score constitutes 50% of the final MIPS score.^{7,8} More than 250 quality measures can be reported in an APM. These measures are divided into 7 categories: 1) process, 2) structure, 3) efficiency, 4) patient engagement and experience, 5) intermediate outcome, 6) outcome, and 7) patient-reported outcome. Reported measures can be found at <https://qpp.cms.gov/mips/quality-measures>. These measures can be reported through approved Qualified Clinical Data Registries when available, electronic health records, and Medicare part B claims, among others. The validated quality measures developed by the American Urogynecologic Society are listed in Table 2.⁹

Ideal quality measures are meaningful to both health care providers and patients and distinguish between low- and high-quality care. Because scores are benchmarked across all health care providers, the better others perform on a given measure, the harder it is to be a high performer. Thus, it is important to develop and expand meaningful urogynecologic quality improvement initiatives. To that end, the AUGS Quality Committee is currently conducting a multi-site retrospective cohort study on quality metrics in anti-incontinence surgery (Quality in Anti-Incontinence Protocol, Table 3). A similar study on preoperative quality measures in pelvic organ prolapse surgery has already been published.¹⁰

In addition to these validated quality measures, AUGS, the American College of Obstetricians and Gynecologists, and the

American Urologic Association have developed guidelines for evaluating uncomplicated SUI, particularly regarding the use of preoperative multichannel urodynamics and cystoscopy.^{11,12} Although specific quality measures regarding the use of these tests have not been established, decreasing use of unnecessary urodynamics could provide significant cost savings without affecting patient outcomes.¹³ Thus, the PRC will further examine and validate current practice patterns to determine how preoperative testing would fit in an aAPM. For example, it is known that evaluation and treatments offered to patients with pelvic organ prolapse are variable.¹⁰ By adhering to evidence-based practice guidelines for SUI E&M, we should be able to standardize practice patterns, reduce costs, and improve quality of care by reducing unindicated testing and procedures.

THE NEED FOR RISK ADJUSTMENT IN AN AAPM FOR STRESS URINARY INCONTINENCE

As the aAPM for SUI is developed, it is understood that no 2 cases are exactly alike. At its simplest, SUI is defined as leakage of urine with coughing, laughing, sneezing, or physical activity. However, patients presenting for SUI E&M can have a wide spectrum of medical comorbidities and surgical histories that may affect outcomes and complications and, therefore, must be considered when designing a treatment plan. In addition, whereas some health care providers may only treat low-complexity patients (ie, no comorbidities or previous incontinence or pelvic surgery), others may see predominantly high-complexity patients. Likely, most FPMRS-trained and board-certified surgeons will see a patient population of mixed complexity (ie, low to high). To account for the potential variability in patient factors, aAPMs typically incorporate risk-adjustment strategies. One possibility is to create an aAPM that only includes low-complexity patients. In that case, higher-complexity patients would be covered in traditional fee-for-service models. Another possibility is to create a tiered aAPM that stratifies patients according to their levels of complexity of medical and surgical risk factors. In either case, it is critical to ensure that health care providers and hospitals that care for predominantly high-risk or high-complexity patients are not penalized in the aAPM and that all patients receive the evaluation and care that they need. Currently, the PRC supports developing a tiered aAPM in which the tiers of care will hedge the increased costs associated with patients with multiple comorbidities or surgical complexity. Ideally, the tiered aAPM will adapt to local-regional practice and payer practice patterns, adjust for varying risk in different patient populations, and adjust for higher care needs and higher risks of failure, complications, and recurrence in high-complexity patients.

PRACTICE CAPABILITIES AND IMPLEMENTATION

Incorporating an aAPM for SUI will require many health care providers to alter their practice management. To succeed in this process, health care providers must have a clear implementation plan, which may require them to incorporate and integrate care across multiple specialties and providers. These may include primary care physicians, general gynecologists, FPMRS specialists, physical therapists with advanced training and education in pelvic floor disorders, and possibly a patient navigator to coordinate care. A successful practice will be able to identify SUI patients who should participate in the aAPM (differentiating them from those with other pelvic floor disorders), appropriately evaluate them, and counsel them about management options. The aAPM will need to reflect the increased work of the primary health care provider (eg, coordinating care) and office staff (eg, calling patients postoperatively to identify issues that could be evaluated in the office instead of the emergency department).

TABLE 3. Proposed Performance and Risk-Adjusted Outcomes Measures for Urinary Incontinence Proposed by the AUGS Quality Committee

Performance Measures

1. Documentation of preoperative POP-Q or Baden-Walker examination before surgery
2. Documentation of discussion of nonsurgical options: pessary or pelvic floor muscle exercises (a.k.a., Kegel), pelvic floor physical therapy, exercise, and weight loss
3. Performance of preoperative cough stress test
4. Performance of preoperative postvoid residual
5. Performance of intraoperative cystoscopy at the time of surgery
6. Use of biologic or synthetic graft

Risk-Adjusted Outcome Measures

1. Rate of admission after discharge from surgery related to medical comorbidity
2. Rate of ureteral injury recognized at the time of surgery and delayed recognition of these injuries
3. Rate of bladder injury recognized at the time of surgery and delayed recognition of these injuries
4. Rate of bowel injury recognized at the time of surgery and delayed recognition of these injuries
5. Perioperative (both intraoperative and postoperative) blood transfusion
6. Hospital length of stay
7. 30-d Readmission rates after surgery
8. 30-d Urinary tract infection rates after surgery
9. 30-d Surgical site infection rates after surgery
10. 1-y Reoperation rates after surgery (may include surgery for mesh exposure/complication, voiding dysfunction, treatment failure, or prolapse surgery)
11. 2-y Reoperation rates following surgery (may include surgery for mesh exposure/complication, voiding dysfunction, treatment failure, or prolapse surgery)

*Denotes an AUGS Choosing Wisely proposed measures to the American Board of Internal Medicine.

TABLE 4. Practice Management Components of the Comprehensive Care of Stress Urinary Incontinence

| Location | Preoperative Care | | | Postoperative Care | | | |
|----------|---|---|---|--|--|---|---|
| | Initial Contact | Initial Visit | Preoperative Work-Up | Surgical Management | Postoperative Care | Revision or Further Treatment | Continuing Care |
| Home | Referral; Call to administrator Insurance | | Patient-initiated calls Patient EMR portal question Patient tries home therapy or vaginal inserts | | Patient-initiated phone calls Patient EMR questions RN initiated calls Additional staff calls | Patient-initiated phone calls Patient EMR questions | Patient-initiated calls or EMR questions |
| Office | Admin screens patients Admin obtains records | MA gets vitals or RN RN/APP/MD examination and consult | PT Consult Preoperative laboratories Preoperative tests CMG, UDS, cystoscopy Preoperative imaging PRN Admin prior authorization Medical Clearance PRN Anesthesia Clearance PRN MD confirms initial surgery plan MD checks clearance | | Postop Void Trial RN visit (ie, ISC training, Foley reinsertion, repeat void trial(s) Post op 2 wk visit MD/APP MD Counseling Postop 6 wk visit Referral to PT Patient requires medication management or further care after 6 weeks | Referral to PT Needs further medical or surgical management Revision of sling or takedown Complications from mesh office or surgical management RN phone calls Imaging PRN Laboratories PRN Urgent clinical evaluation | Further follow-up for other PFDs Dietician referral Post-surgery counseling |
| ED | | | | | Urgent evaluation PRN Imaging PRN | | |
| Hospital | | | | OR case, prioritize MIS, same day discharge postop day 0 | Urgent admission PRN Imaging PRN Medical consults PRN | | |

Abbreviations: APP, Advanced Practice Provider; CMG, cystometrogram; EMR, Electronic medical record; MA, Medical assistant; MIS, Minimally invasive surgery; PFD, Pelvic floor disorders; PT, Physical therapy; UDS, urodynamics;

Although implementing an aAPM will be challenging, doing so should help health care providers coordinate care, avoid unnecessary preoperative testing and use less costly options when indicated, prioritize conservative treatments over more costly ones, and reduce intraoperative and postoperative complications, thus improving quality of care and reducing costs. It is anticipated that an aAPM for SUI will guide health care providers to avoid unnecessary evaluation costs and first offer nonsurgical treatments, such as physical therapy, when appropriate. During nonsurgical management, it will be important to thoroughly document evaluations and therapies and to assess treatment response with standardized, validated patient-centered outcome measurement tools outcomes. A health care provider or patient navigator can then follow up with patients to assess their symptoms and use patient-centered educational materials to ensure the patients understand the treatment options if their symptoms are not resolved to their satisfaction. If surgical correction does occur, a pathway should be in place to allow for appropriate postoperative care and necessary follow-up or management of other associated pelvic floor disorders. Table 4 describes the various patient contacts that may occur during the management of SUI. Capturing the different contact points throughout care will enhance aAPM implementation and limit hospital and emergency department visits.

Although implementing an aAPM for SUI will be challenging, many physicians have successfully implemented aAPMs for other clinical issues such as joint replacement, end-stage renal disease, and chemotherapy. In surveys, these physicians note that timely and consistent feedback from either the payer or electronic medical record greatly helped them improve and inform their practice.¹⁴ Finally, we note that the process of implementing the aAPM for SUI will be an iterative, data-driven process.

ONGOING AND FUTURE DIRECTIONS

Thus far, the AUGS PRC has developed an APM framework as described above, obtained CMS claims data related to SUI, and begun initial data analyses. Once these analyses are complete, a decision and cost-effectiveness analysis will be used to model the data. It may be found that health care providers are currently over-using certain tests or treatments or using them when not indicated. This information will be used to inform to the model and, eventually, begin educational initiatives and produce a publication focused on appropriate use and adherence to clinical pathways. Additionally, in light of findings from the CMS claims data, a re-review of the existing quality metrics will be performed to determine whether additional or alternative measures need to be included to promote high-quality care and adherence to the model.

Once the aAPM is ready for beta testing in additional data sets, it is hoped that interested payers will run the model with their beneficiary data and provide performance feedback so that the aAPM may be revised as needed. It is anticipated that the SUI aAPM will be revised over time to reflect changes in evidence-based practices, societal factors, and health care policy. Additionally, the SUI aAPM will need to be modified to regional or local practice and payer patterns and risk adjustments. We plan to present our initial findings from analyzing CMS data, our initial aAPM, and results of applying the aAPM to CMS data at the annual AUGS meetings. Subsequently, we plan to publish these findings in 2 separate reports, including important findings from the CMS analyzed in the first and the second describing the proposed aAPM for SUI based on the data analysis and modeling.

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