ILLINOIS STATE MEDICAL SOCIETY

Resolution 09.2018-02
(A-19)

Introduced by: Craig A. Backs, M.D, ISMS Member

Subject: ICD Code for Patient Harm From Payer Interference

Referred to: Medical Legal Council

Whereas, the harm to patients caused by delayed implementation of prescribed treatment or compromise in treatments or testing prompted by payers that result in switching for reasons other than efficacy or toxicity cannot be quantified because its role cannot be coded by our current ICD system; and

Whereas, other contributors to patient and public health harm are identified by the mining of data from ICD administrative codes, including but not limited to infections, poisons, assaults, insect bites, trauma, infections and lifestyle factors; therefore, be it

RESOLVED, that the Illinois State Medical Society introduce a resolution to the American Medical Association (AMA) House of Delegates asking the AMA to support the creation and implementation of an ICD code(s) to identify administrator or payer influence that affects treatment and leads to or contributes to, directly or indirectly, patient harm.

Fiscal Note:

N/A

Existing ISMS policy related to this issue:

NOTE: ISMS endorsed the AMA's Prior Authorization and Utilization Management Reform Principles, a document carefully crafted by a coalition of health care organizations, including representatives from physician organizations, hospitals, pharmacists and patient groups.

House of Delegates adopted Substitute Resolution B210 (A-17) in lieu of Resolution B210 (A-17) and Resolution B212 (A-17), which states: RESOLVED, that ISMS formally adopt and incorporate the AMA Prior Authorization and Utilization

Management Reform Principles into its policy manual; and be it further RESOLVED, that ISMS widely share these principles with governmental and private sector third party payers, as appropriate, and specifically in Illinois with the Department of Insurance (DOI) and Department of Healthcare and Family Services (DHFS), to urge all third party payers and oversight agencies to adopt guidelines that comply with these principles; and be it further RESOLVED, that ISMS seek or cause to be introduced specific state legislative remedies, as necessary, to cause Illinois third party payers to implement the utilization and prior approval practices addressed in these principles. (HOD 2018)

Board of Trustees approved that ISMS cause the introduction of legislation to require Medicaid managed care companies to utilize a uniform drug formulary. (BOT 2017 - JAN)

Board of Trustees adopted Substitute Resolution 38 (A-07), Opposition to Pre-authorization for Prescriptions, as amended: that the ISMS support legislation to regulate the activities of pharmacy benefit managers (PBMs), including prohibiting them from switching properly prescribed medications to another therapeutic brand or generic without the specific approval of the prescriber; that the ISMS, through its Division of Member Advocacy, provide assistance to members who experience unnecessary hassles with the administrative policies of third party payers and PBMs with respect to drug benefit coverage, and create a mechanism to assist and encourage members to bring forward complaints about pharmacists or PBMs who inappropriately switch properly prescribed medications; that the ISMS urge PBMs and third party payers to make all policies related to drug coverage and formulary usage transparent for prescribers and patients; that the AMA be directed to urge PBMs and Medicare Part D contractors to use evidence-based criteria for more uniformity in their coverage policies and to streamline any prior approval or exception processes; and that the ISMS policy support doctors being reimbursed for time spent reauthorizing patient prescriptions. (BOT 2008-APR)

It is the policy of ISMS to support open drug formularies and to recognize that many formularies are not open, and where formularies are restricted, that they be restricted in accordance with the Principles of a Sound Drug Formulary System. (HOD 2001; BOT 2001-JUN; Last BOT Review 2014)

In the event that a pharmacy reports back to the prescriber that a specific drug is not or no longer on the formulary or needs pre-authorization, then the pharmacy will consult the insurer for formulary alternatives, provide notice of the alternatives to the prescriber, and gather the prescriber's authorization for the substitution within 72 hours either by telephone, facsimile, or through an electronic prescribing system. (HOD 2014; Reaffirmed 2015)

Pre-admission, pre-procedure and continued stay review should not result in a denial without patient-authorized, direct consultation, between the ordering physician and the reviewing physician in the same specialty of medicine. (HOD 1991; Last BOT Review 2013)

The Illinois State Medical Society supports the principle that all entities engaged in the practice of private Utilization Review in Illinois be regulated by the State. (HOD 1992; Last BOT Review 2011)

Pre-certification requirements should allow reasonable time and opportunity for contact with the admitting physician; no pre-certification requirements should apply in any emergency situation; and any action to obtain any utilization review information while a patient is being treated for an emergency situation should be opposed. (HOD 1992; Last BOT Review 2013)

It is the policy of the Society to require third party payors to have notices of payment and denial signed by the specific responsible employee denying payment by the third party payor; that such third party payors provide on the notices an address and an accessible phone number of the responsible person to answer for denying claims; and that no notices of allegations of fraud be sent until the denied party has responded; and that state law provide for oversight of third party payors to determine that they comply with such requirements. (HOD 1996; Reaffirmed 2015; Last BOT Review 2013)

ISMS supports the position that all denials of tests or procedures by third-party payors should be made only by licensed physicians and that decisions to approve or deny tests or procedures by managed care organizations constitute the practice of medicine and must be done only by licensed physicians. (HOD 1997; Reaffirmed 2015; Last BOT Review 2013)

House of Delegates adopted Res. 95 (A-97) which directed that the Society seek to pass into law a bill that incorporates the following principles: (1) all denials of tests or procedures by third-party payors be made only by licensed physicians; and (2) decisions to approve or deny tests or procedures by managed care organizations constitute the practice of medicine and must be done only by licensed physicians. (HOD 1997)

Board of Trustees approved causing the introduction of legislation amending the Illinois Insurance Code and the Managed Care Reform and Patient Rights Act to define “medical necessity” as any health care treatment, device, drugs or supplies recommended, ordered or provided by a health care professional in the evaluation and treatment of disease, condition, or injury consistent with the applicable standard of care, and to deem it an unfair and deceptive practice for health insurance plans to refer to any

policy, contract, agreement or explanation of benefits to designate services as medically necessary or unnecessary. (BOT 2016-JAN)

American Medical Association

American Academy of Child and Adolescent Psychiatry

American Academy of Dermatology

American Academy of Family Physicians

American College of Cardiology

American College of Rheumatology

American Hospital Association

American Pharmacists Association

American Society of Clinical Oncology

Arthritis Foundation

Colorado Medical Society

Medical Group Management Association

Medical Society of the State of New York

Minnesota Medical Association

North Carolina Medical Society

Ohio State Medical Association

Washington State Medical Association

Prior Authorization and Utilization Management Reform Principles

Patient-centered care has emerged as a major common goal across the health care industry. By empowering patients to play an active role in their care and assume a pivotal role in developing an individualized treatment plan to meet their health care needs, this care model can increase patients' satisfaction with provided services and ultimately improve treatment quality and outcomes.

Yet despite these clear advantages to adopting patient-centered care, health care providers and patients often face significant obstacles in putting this concept into practice. Utilization management programs, such as prior authorization and step therapy, can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. The very manual, time-consuming processes used in these programs burden providers (physician practices, pharmacies and hospitals) and divert valuable resources away from direct patient care. However, health plans and benefit managers contend that utilization management programs are employed to control costs and ensure appropriate treatment.

Recognizing the investment that the health insurance industry will continue to place in these programs, a multi-stakeholder group representing patients, physicians, hospitals and pharmacists (see organizations listed in left column) has developed the following principles on utilization management programs to reduce the negative impact they have on patients, providers and the health care system. **This group strongly urges health plans, benefit managers and any other party conducting utilization management ("utilization review entities"), as well as accreditation organizations, to apply the following principles to utilization management programs for both medical and pharmacy benefits.** We believe adherence to these principles will ensure that patients have timely access to treatment and reduce administrative costs to the health care system.

Clinical Validity

1. Health care providers want nothing more than to provide the most clinically appropriate care for each individual patient. Utilization management programs must therefore have a clinically accurate foundation for provider adherence to be feasible. Cost-containment provisions that do not have proper medical justification can put patient outcomes in jeopardy.

Principle #1: Any utilization management program applied to a service, device or drug should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.

2. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the provider in consultation with his/her patient. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances, for example, may necessitate an alternative treatment. Failure to account for this can obstruct proper patient care.

Principle #2: Utilization management programs should allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.

3. Adverse utilization management determinations can prevent access to care that a health care provider, in collaboration with his/her patient and the care team, has determined to be appropriate and medically necessary. As this essentially equates to the practice of medicine by the utilization review entity, it is imperative that these clinical decisions are made by providers who are at least as qualified as the prescribing/ordering provider.

Principle #3: Utilization review entities should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues.

Continuity of Care

4. Patients forced to interrupt ongoing treatment due to health plan utilization management coverage restrictions could experience a negative impact on their care and health. In the event that, at the time of plan enrollment, a patient's condition is stabilized on a particular treatment that is subject to prior authorization or step therapy protocols, a utilization review entity should permit ongoing care to continue while any prior authorization approvals or

step-therapy overrides are obtained.

Principle #4: Utilization review entities should offer a minimum of a 60-day grace period for any step-therapy or prior authorization protocols for patients who are already stabilized on a particular treatment upon enrollment in the plan. During this period, any medical treatment or drug regimen should not be interrupted while the utilization management requirements (e.g., prior authorization, step therapy overrides, formulary exceptions, etc.) are addressed.

5. Many patients carefully review formularies and coverage restrictions prior to purchasing a health plan product in order to ensure they select coverage that best meets their medical and financial needs. Unanticipated changes to a formulary or coverage restriction throughout the plan year can negatively impact patients' access to needed medical care and unfairly reduce the value patients receive for their paid premiums.

Principle #5: A drug or medical service that is removed from a plan's formulary or is subject to new coverage restrictions after the beneficiary enrollment period has ended should be covered without restrictions for the duration of the benefit year.

6. Many conditions require ongoing treatment plans that benefit from strict adherence. Recurring prior authorizations requirements can lead to gaps in care delivery and threaten a patient's health.

Principle #6: A prior authorization approval should be valid for the duration of the prescribed/ordered course of treatment.

7. Many utilization review entities employ step therapy protocols, under which patients are required to first try and fail certain therapies before qualifying for coverage of other treatments. These programs can be particularly problematic for patients—such as those purchasing coverage on the individual marketplace—who change health insurance on an annual basis. Patients who change health plans are often required to disrupt their current treatment to retry previously failed therapeutic regimens to meet step therapy requirements for the new plan. Forcing patients to abandon effective treatment and repeat therapy that has already been proven ineffective under other plans' step therapy protocols delays care and may result in negative health outcomes.

Principle #7: No utilization review entity should require patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.

Transparency and Fairness

8. Prior authorization requirements and drug formulary changes can have a direct impact on patient care by creating a delay or altering the course of treatment. In order to ensure that patients and health care providers are fully informed while purchasing a product and/or making care decisions, utilization review entities need to be transparent about all coverage and formulary restrictions and the supporting clinical documentation needed to meet utilization management requirements.

Principle #8: Utilization review entities should publically disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process. Additionally, utilization review entities should clearly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy override request.

9. Incorporation of accurate formulary data and prior authorization and step therapy requirements into electronic health records (EHRs) is critical to ensure that providers have the requisite information at the point of care. When prescription claims are rejected at the pharmacy due to unmet prior authorization requirements, treatment may be delayed or completely abandoned, and additional administrative burdens are imposed on prescribing providers and pharmacies/pharmacists.

Principle #9: Utilization review entities should provide, and vendors should display, accurate, patient-specific, and up-to-date formularies that include prior authorization and step therapy requirements in electronic health record (EHR) systems for purposes that include e-prescribing.

10. Data are critical to evaluating the effectiveness, potential impact and costs of prior authorization processes on patients, providers, health insurers and the system as a whole; however, limited data are currently made publically available for research and analysis. Utilization review entities need to provide industry stakeholders with relevant data, which should be used to improve efficiency and timely access to clinically appropriate care.

Principle #10: Utilization review entities should make statistics regarding prior authorization approval and denial rates available on their website (or another publically available website) in a readily accessible format. The statistics shall include but are not limited to the following categories related to prior authorization requests:

- **i. Health care provider type/specialty;**
- **ii. Medication, diagnostic test or procedure;**
- **iii. Indication;**
- **iv. Total annual prior authorization requests, approvals and denials;**
- **v. Reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and**
- **vi. Denials overturned upon appeal.**

These data should inform efforts to refine and improve utilization management programs.

11. A planned course of treatment is the result of careful consideration and collaboration between patient and physician. A utilization review entity's denial of a drug or medical service requires deviation from this course. In order to promote provider (physician practice, hospital and pharmacy) and patient understanding and ensure appropriate clinical decision-making, it is important that utilization review entities provide specific justification for prior authorization and step therapy override denials, indicate any covered alternative treatment and detail any available appeal options.

Principle #11: Utilization review entities should provide detailed explanations for prior authorization or step therapy override denials, including an indication of any missing information. All utilization review denials should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment and detail the provider's appeal rights.

Timely Access and Administrative Efficiency

12. The use of standardized electronic prior authorization transactions saves patients, providers and utilization review entities significant time and resources and can speed up the care delivery process. In order to ensure that prior authorization is conducted efficiently for all stakeholders, utilization review entities need to complete all steps of utilization management processes through NCPDP SCRIPT ePA transactions for pharmacy benefits and the ASC X12N 278 Health Care Service Review Request for Review and Response transactions for medical services benefits. Proprietary health plan web-based portals do not represent efficient automation or true administrative simplification, as they require health care

providers to manage unique logins/passwords for each plan and manually re-enter patient and clinical data into the portal.

Principle #12: A utilization review entity requiring health care providers to adhere to prior authorization protocols should accept and respond to prior authorization and step-therapy override requests exclusively through secure electronic transmissions using the standard electronic transactions for pharmacy and medical services benefits. Facsimile, proprietary payer web-based portals, telephone discussions and nonstandard electronic forms shall not be considered electronic transmissions.

13. Providers have encountered instances where utilization review entities deny payment for previously approved services or drugs based on criteria outside of the prior authorization review process (e.g., eligibility issues, medical policies, etc.). These unexpected payment denials create hardship for patients and additional administrative burdens for providers.

Principle #13: Eligibility and all other medical policy coverage determinations should be performed as part of the prior authorization process. Patients and physicians should be able to rely on an authorization as a commitment to coverage and payment of the corresponding claim.

14. Significant time and resources are devoted to completing prior authorization requirements to ensure that the patient will have the requisite coverage. If utilization review entities choose to use such programs, they need to honor their determinations to avoid misleading and further burdening patients and health care providers. Prior authorization must remain valid and coverage must be guaranteed for a sufficient period of time to allow patients to access the prescribed care. This is particularly important for medical procedures, which often must be scheduled and approved for coverage significantly in advance of the treatment date.

Principle #14: In order to allow sufficient time for care delivery, a utilization review entity should not revoke, limit, condition or restrict coverage for authorized care provided within 45 business days from the date authorization was received.

15. In order to ensure that patients have prompt access to care, utilization review entities need to make coverage determinations in a timely manner. Lengthy processing times for prior authorizations can delay necessary treatment, potentially creating pain and/or medical complications for patients.

Principle #15: If a utilization review entity requires prior authorization for non-urgent care, the entity should make a determination and notify the provider within 48 hours of obtaining all necessary information. For urgent care, the determination should be made within 24 hours of obtaining all necessary information.

16. When patients receive an adverse determination for care, the patient (or the physician on behalf of the patient) has the right to appeal the decision. The utilization review entity has a responsibility to ensure that the appeals process is fair and timely.

Principle #16: Should a provider determine the need for an expedited appeal, a decision on such an appeal should be communicated by the utilization review entity to the provider and patient within 24 hours. Providers and patients should be notified of decisions on all other appeals within 10 calendar days. All appeal decisions should be made by a provider who (a) is of the same specialty, and subspecialty, whenever possible, as the prescribing/ordering provider and (b) was not involved in the initial adverse determination.

17. Prior authorization requires administrative steps in advance of the provision of medical care in order to ensure coverage. In emergency situations, a delay in care to complete administrative tasks related to prior authorization could have drastic medical consequences for patients.

Principle #17: Prior authorization should never be required for emergency care.

18. There is considerable variation between utilization review entities' prior authorization criteria and requirements and extensive use of proprietary forms. This lack of standardization is associated with significant administrative burdens for providers, who must identify and comply with each entity's unique requirements. Furthermore, any clinically based utilization management criteria should be similar—if not identical—across utilization review entities.

Principle #18: Utilization review entities are encouraged to standardize criteria across the industry to promote uniformity and reduce administrative burdens.

Alternatives and Exemptions

19. Broadly applied prior authorization programs impose significant administrative burdens on all health care providers, and for those providers with a clear history of appropriate resource utilization and high prior authorization approval rates, these burdens become especially unjustified.

Principle #19: Health plans should restrict utilization management programs to "outlier" providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix and other relevant factors.

20. Prior authorization requirements are a burdensome way of confirming clinically appropriate care and managing utilization, adding administrative costs for all stakeholders across the health care system. Health plans should offer alternative, less costly options to serve the same functions.

Principle #20: Health plans should offer providers/practices at least one physician-driven, clinically based alternative to prior authorization, such as but not limited to "gold-card" or "preferred provider" programs or attestation of use of appropriate use criteria, clinical decision support systems or clinical pathways.

21. By sharing in the financial risk of resource allocation, providers engaged in new payment models are already incented to contain unnecessary costs, thus rendering prior authorization unnecessary.

Principle #21: A provider that contracts with a health plan to participate in a financial risk-sharing payment plan should be exempt from prior authorization and step-therapy requirements for services covered under the plan's benefits.