AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: XX
(A-19)

Introduced by: American College of Rheumatology
American Academy of Ophthalmology
American Association of Clinical Endocrinologists
American Society of Clinical Oncology

Subject: Medicare Advantage Step Therapy

Referred to: Reference Committee ___
(_____, MD, Chair)

Whereas, The rescinded September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services and the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule by the Centers for Medicare & Medicaid Services threatens to reduce access to innovative and complex drugs including biologics and chemotherapy, which have been a lifeline for Medicare patients with chronic and life-threating conditions including cancer, rheumatoid arthritis, Crohn's disease, ulcerative colitis, macular degeneration, multiple sclerosis, osteoporosis, primary immunodeficiency diseases, and others; and

Whereas, new guidance allows MA plans to use step therapy for Part B drugs, beginning January 1, 2019; and

Whereas, The CMS-proposed patient safeguards would not go into effect until 2020, leaving vulnerable patients unprotected from harmful step therapy practices; and

Whereas, the timing of the regulatory guidances and proposed rules create a year gap of protections for patients in 2019; and

Whereas, Step therapy frequently disrupts continuity of care by requiring patients to stop an effective therapy and switch to another due to formulary or protocol changes; and

Whereas, Stopping and restarting certain medicines may cause the treatments to fail due to immunogenicity or cause dangerous reactions when the medication is re-initiated; and

Whereas, More details on exceptions to Step Therapy protocols are needed; and

Whereas, the recent Part D-MA final rule does not include additional safeguards for patients in the 2019 plan year; therefore be it

RESOLVED, That our American Medical Association will work with CMS to immediately publish guidance to plans that lays out, at minimum, the patient safeguards proposed/finalized in the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket*

Expenses proposed rule so that beneficiaries have some protections in 2019, as well as additional clarifying language on exceptions not limited to the following principles:

1. That the provider determines if a patient "fails" a treatment, not another entity such as the insurance company.
2. Exception if the treatment is contraindicated.
3. Exception if the provider determines the treatment is likely to be ineffective.
4. Exception if the provider determines the treatment is likely to cause a harmful reaction.
5. Exception for those whose life could be in jeopardy or physical or sensory function irreparably harmed.
6. Exception if the provider and patient believe the treatment is likely to impede the patient's ability to perform daily activities or responsibilities and/or adhere to the treatment plan.
7. Clarification that a patient with a second eye event should be considered an established patient and therefore should not be subject to step therapy policies for the second eye event.
8. Preclude any unwritten, implicit step therapy that is handled through a different utilization management process such as prior authorization.
9. Provide adequate safeguards to maintain coverage for patients currently stable on a medication, even if the last dose was over 6 months prior; and be it further

RESOLVED, That if CMS does not respond to stakeholder input and publish guidance according to these and other principles, our AMA will support and actively work to advance Congressional action to provide patients safeguards in the 2019 plan year.

Fiscal Note:

Received:

RELEVANT AMA POLICY

Medicare Advantage Step Therapy D-320.984
Our AMA will continue strong advocacy for the rejection of step therapy in Medicare Advantage plans and impede the implementation of the practice before it takes effect on January 1, 2019.

Clinical Practice Guidelines and Clinical Quality Improvement Activities H-320.949
Our AMA adopts the following principles for the development and application of utilization management guidelines:
(1) The criteria or guidelines used for utilization management shall be based upon sound clinical evidence and consider, among other factors, the safety and effectiveness of diagnosis or treatment, and must be age appropriate.
(2) These utilization management guidelines and the criteria for their application shall be developed with the participation of practicing physicians.
(3) Appropriate data, clinical evidence, and review criteria shall be available on request.
(4) When used by health plans or health care organizations, such criteria must allow variation and take into account individual patient differences and the resources available in the particular health care system or setting to provide recommended care. The guidelines should also include a statement of their limitations and restrictions.
(5) Patients and physicians shall be able to appeal decisions based on the application of utilization management guidelines.
(6) The competence of non-physician reviewers and the availability of same-specialty peer review must be delineated and assured.

(7) Maintaining the best interests of the patient uppermost, the final decision to discharge a patient, or any other patient management decision, remains the prerogative of the physician.

Emerging Trends in Utilization Management H-320.958
The AMA will: (1) maintain a leadership role in coordinating private sector efforts to develop and refine utilization management and quality assessment programs; (2) establish an active role in the development of any national utilization management and quality assessment programs that are proposed in the ongoing health system reform debate; and (3) advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession

Prior Authorization and Utilization Management Reform H-320.939
1. Our AMA will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
3. Our AMA supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm.