AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 227
(I-22)

Introduced by: Women Physicians Section

Subject: Access to Methotrexate Based on Clinical Decisions

Referred to: Reference Committee B

Whereas, Methotrexate is a medication used to treat many medical conditions including, but not limited to, cancer, psoriasis, myasthenia gravis, and various autoimmune diseases;¹,²,³ and

Whereas, Methotrexate has remained a cornerstone in treatment specifically for rheumatoid arthritis (RA) and common rheumatic disorders with 90% of RA patients using methotrexate alone or in combination with other medications at some point in their treatment;⁴ and

Whereas, Autoimmune disorders are twice as prevalent in women, and RA rates are typically two-to-three times higher in women than men;⁵,⁶ and

Whereas, Methotrexate may also be used off-label, alone or in combination with mifepristone as a non-invasive alternative method for early medical pregnancy terminations and treatment of ectopic pregnancies;⁷,⁸ and

Whereas, The Supreme Court ruling in Dobbs v. Jackson Women’s Health Organization revoked the constitutional right to abortion;⁹ and

Whereas, Because methotrexate “can cause a pregnancy to terminate, some pharmacists in states that have added further restrictions that limit or ban abortions may hesitate to fill methotrexate prescriptions for women of childbearing age because of legal concerns”;¹⁰,¹¹ and

Whereas, Two large United States pharmacy chains have “instructed their pharmacists to confirm methotrexate will not be used to terminate a pregnancy before dispensing it to people in states that ban abortion in many circumstances,”;¹² and

Whereas, As an example of numerous accounts of refusal of methotrexate, in interviews with CNN, a Maryland woman with Crohn’s disease said her health insurance plan informed her they would no longer cover her methotrexate prescription, and a Virginia woman with lupus said her rheumatologist told her she would need to be weaned off methotrexate and switched to another drug due to legal concerns;¹¹,¹⁴ and

Whereas, Restricting access to methotrexate based on non-clinical decisions can lead to unintended consequences, including worsening health conditions, suffering, and death for patients that cannot safely access methotrexate; and

Whereas, Restricting access to methotrexate may impact the health and safety of female patients, who are disproportionately affected by health conditions that could be treated using methotrexate; and
Whereas, Methotrexate is on the World Health Organization’s list of essential medicines for a basic health-care system due to efficacy, safety, and cost-effectiveness; and

Whereas, Our American Medical Association issued a statement regarding state laws that limit patient access to medically necessary treatment and impede use of professional judgment by physicians; therefore be it

RESOLVED, That our American Medical Association work to create a formal process to review pharmaceutical practices related to refusal of methotrexate and other drugs on the basis that it could be used off-label for pregnancy termination (Directive to Take Action); and be it further

RESOLVED, That our AMA work to provide educational guidance on state-specific laws that have impacted the distribution of methotrexate given post Dobbs vs. Jackson Women’s Health Organization restrictions. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/12/22

REFERENCES:
11. Upham B. Women with RA, other diseases may have trouble accessing methotrexate because of abortion restrictions. 2022 July; https://www.everydayhealth.com/rheumatoid-arthritis/women-with-ra-may-have-trouble-accessing-methotrexate-due-to-abortion-restrictions/

RELEVANT AMA POLICY

Patient Access to Treatments Prescribed by Their Physicians H-120.988
1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate ’off-label’ uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored
promotions remain under FDA regulation.

3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.

4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).

5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.

6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

Establishing A Task Force to Preserve the Patient-Physician Relationship When Evidence-Based, Appropriate Care Is Banned or Restricted G-605.009

1. Our AMA will convene a task force of appropriate AMA councils and interested state and medical specialty societies, in conjunction with the AMA Center for Health Equity, and in consultation with relevant organizations, practices, government bodies, and impacted communities for the purpose of preserving the patient-physician relationship.

2. This task force, which will serve at the direction of our AMA Board of Trustees, will inform the Board to help guide organized medicine's response to bans and restrictions on abortion, prepare for widespread criminalization of other evidence-based care, implement relevant AMA policies, and identify and create implementation-focused practice and advocacy resources on issues including but not limited to:
   a. Health equity impact, including monitoring and evaluating the consequences of abortion bans and restrictions for public health and the physician workforce and including making actionable recommendations to mitigate harm, with a focus on the disproportionate impact on under-resourced, marginalized, and minoritized communities;
   b. Practice management, including developing recommendations and educational materials for addressing reimbursement, uncompensated care, interstate licensure, and provision of care, including telehealth and care provided across state lines;
   c. Training, including collaborating with interested medical schools, residency and fellowship programs, academic centers, and clinicians to mitigate radically diminished training opportunities;
   d. Privacy protections, including best practice support for maintaining medical records privacy and confidentiality, including under HIPAA, for strengthening physician, patient, and clinic security measures, and countering law enforcement reporting requirements;
   e. Patient triage and care coordination, including identifying and publicizing resources for physicians and patients to connect with referrals, practical support, and legal assistance;
   f. Coordinating implementation of pertinent AMA policies, including any actions to protect against civil, criminal, and professional liability and retaliation, including criminalizing and penalizing physicians for referring patients to the care they need; and
   g. Anticipation and preparation, including assessing information and resource gaps and creating a blueprint for preventing or mitigating bans on other appropriate health care, such as gender affirming care, contraceptive care, sterilization, infertility care, and management of ectopic pregnancy and spontaneous pregnancy loss and pregnancy complications.

Citation: Res. 621, A-22