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3 Title: Off-Label Policy  
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5 Introduced by: David Whalen, MD, MPA, for the Kent County Delegation  
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7 Original Author: Gerald Lee, MD  
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9 Referred To: Reference Committee A  
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11 House Action: **APPROVED AS AMENDED**  
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14 Whereas, "one size does not fit all" and a physician is in a unique position to discuss  
15 risk/benefits and evaluate a specific medication/dose for a specific individual, and  
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17 Whereas, physicians have the best interests of the individual at the forefront, education to  
18 evaluate studies, and the ability to move more quickly than official channels especially when profits  
19 are a determinant of such approval, and  
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21 Whereas, new data is constantly becoming available affecting new treatments, dosage,  
22 conditions, and situations, and  
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24 Whereas, the American Medical Association (AMA) policy, Patient Access to Treatments  
25 Prescribed by Their Physicians H-120.988, affirms the autonomous clinical decision-making  
26 authority of a physician and the ability of that a physician to lawfully use an FDA approved drug  
27 product or medical device for an off-label indication when such use is based upon sound scientific  
28 evidence or sound medical opinion; supports the need for physicians to have access to accurate  
29 and unbiased information about off-label uses of drugs and devices; supports the dissemination of  
30 generally available, unedited, independently derived, peer reviewed, scientifically sound, and  
31 truthful information about off-label uses by manufacturers to physicians; recognizes the obligations  
32 of physicians to interpret and put into context information received from any source, including  
33 pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-  
34 label use); supports the addition to FDA-approved labeling those uses of drugs for which safety  
35 and efficacy have been demonstrated; and, supports the continued authorization, implementation,  
36 and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity  
37 Act; therefore be it  
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39 RESOLVED: That MSMS support AMA Policy, "Patient Access to Treatments Prescribed  
40 by Their Physicians H-120.988" as a basic medical right and responsibility of a physician to  
41 provide the best care available to our patients; and be it further  
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43 RESOLVED: That the Michigan Delegation to the American Medical Association (AMA)  
44 ask our AMA to amend AMA Policy, "Patient Access to Treatments Prescribed by Their  
45 Physicians H-120.988." by addition as follows:  
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47 Patient Access to Treatments Prescribed by Their Physicians H-120.988

- 48 1. Our AMA confirms its strong support for the autonomous clinical decision-making authority  
49 of a physician and that a physician may lawfully use an FDA approved drug product or medical  
50 device for an off-label indication when such use is based upon sound scientific evidence or  
51 sound medical opinion; and affirms the position that, when the prescription of a drug or use of  
52 a device represents safe and effective therapy, third party payers, including Medicare, should  
53 consider the intervention as clinically appropriate medical care, irrespective of labeling, should  
54 fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover  
55 appropriate 'off-label' uses of drugs on their formulary.
- 56 2. Our AMA strongly supports the important need for physicians to have access to accurate  
57 and unbiased information about off-label uses of drugs and devices, while ensuring that  
58 manufacturer-sponsored promotions remain under FDA regulation.
- 59 3. Our AMA supports the dissemination of generally available information about off-label uses  
60 by manufacturers to physicians. Such information should be independently derived, peer  
61 reviewed, scientifically sound, and truthful and not misleading. The information should be  
62 provided in its entirety, not be edited or altered by the manufacturer, and be clearly  
63 distinguished and not appended to manufacturer-sponsored materials. Such information may  
64 comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book  
65 chapters should not focus on any particular drug. Dissemination of information by  
66 manufacturers to physicians about off-label uses should be accompanied by the approved  
67 product labeling and disclosures regarding the lack of FDA approval for such uses, and  
68 disclosure of the source of any financial support or author financial conflicts.
- 69 4. Physicians have the responsibility to interpret and put into context information received  
70 from any source, including pharmaceutical manufacturers, before making clinical decisions  
71 (e.g., prescribing a drug for an off-label use).
- 72 5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for  
73 which safety and efficacy have been demonstrated.
- 74 6. Our AMA supports the continued authorization, implementation, and coordination of the  
75 Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.
- 76 **7. Our AMA supports physician autonomy with regard to deciding appropriate dosing.**  
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79 WAYS AND MEANS COMMITTEE FISCAL NOTE: \$1,000-\$2,000 for new MSMS policy.

#### **Relevant MSMS Policy:**

##### **Unproven Therapeutic Substances**

MSMS opposes substituting political considerations for scientific investigation and conclusions for therapeutic substances. However, if political considerations support unproven medical decisions and/or principles, they should be evaluated on an experimental basis following standard experimental drug protocol or as approved by the FDA.

#### **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.