Title of Rule: Revision to the DMEPOS Rule Concerning Pharmacists Prescribing COVID-19 at-home over-the-counter tests, Section 8.590
Rule Number: MSB 22-01-12-C
Division / Contact / Phone: Health Programs Office / Haylee Rodgers / 9467

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   The purpose of this rule is to allows pharmacists to prescribe at-home over-the-counter COVID-19 tests for reimbursement under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit. The basis of this rule is that CMS has mandated coverage of these tests which are available at pharmacies. Pharmacies are enrolled as DMEPOS providers and can bill for the tests, however a prescription is required.

2. An emergency rule-making is imperatively necessary

   ☒ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

   This rule is necessary to comply with a federal mandate to cover at-home over-the-counter COVID-19 tests.

3. Federal authority for the Rule, if any:

   1905(7) SSA

4. State Authority for the Rule:

   State Plan: Attachment 3.1-A 7.g. and Attachment 4.19-B
   Colorado Statute: CRS 25.5-4-416

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021)

Initial Review Final Adoption
Proposed Effective Date **1/14/2022** Emergency Adoption **1/14/2022**
DOCUMENT #12

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   All members will be affected by, and benefit from, this rule as it will allow them to receive these tests from pharmacies without a prescription from their physician. Pharmacies enrolled as DMEPOS providers will benefit from this rule as it will allow them to be reimbursed for these tests.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   DMEPOS Pharmacy providers will receive reimbursement when they submit claims for at-home over-the-counter COVID-19 tests. Members will not have to pay out of pocket for these tests as they will be covered benefits. This rule serves the larger public health objective of ensuring testing is available to everyone.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   This rule revision will incur new costs associated with the mandated coverage of these tests.

4. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no other methods that are less costly or less intrusive to achieve the purpose of the proposed rule.

5. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   There is no alternative method for achieving the goal of having these tests covered at a pharmacy which does not involve allowing pharmacists to prescribe the test.

1 **8.590 DURABLE MEDICAL EQUIPMENT AND DISPOSABLE MEDICAL SUPPLIES**

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4 **8.590.2 BENEFITS**

5 8.590.2.A. All covered DME and Supplies shall, at a minimum, be:

6 1. A Medical Necessity; and

7 2. Prescribed by a physician and, when applicable, recommended by an appropriately
8 licensed practitioner.

9 3. At-home over-the-counter COVID-19 tests may be prescribed by a licensed pharmacist.

10 8.590.2.B. DME and Supplies for Members Residing in Facilities

11 1. DME and Supplies for members residing in a hospital, nursing facility or other facility, are
12 provided by those facilities and reimbursed as part of the per diem rate. DME and
13 Supplies shall not be separately billed, except under the following circumstances:

14 a. The member is within fourteen days of discharge, and

15 b. Prior authorization or training are needed to assist the member with equipment
16 usage, and

17 c. The equipment is needed immediately upon discharge from the facility.

18 2. Repairs and modifications to member owned DME, not required as part of the per diem
19 reimbursement, shall be provided to members residing in a hospital, nursing facility or
20 other facility receiving per diem Medicaid reimbursement.

21 3. Prosthetic or Orthotic Devices may be provided to members residing in a hospital,
22 nursing facility or other facility receiving per diem Medicaid reimbursement if Prosthetic or
23 Orthotic benefits are not included in the facility's per diem rate.

24 8.590.2.C. DME and Supplies shall not be duplicative or serve the same purpose as items already
25 utilized by the member unless it is medically required for emergency or backup support. Backup
26 equipment shall be limited to one.

27 8.590.2.D. All DME and Supplies reimbursed for by the Department shall become the property of the
28 member unless the member and provider are notified otherwise by the Department at the time of
29 purchase.

30 8.590.2.E. Rental equipment shall be provided if the Department determines it to be cost effective
31 and Medically Necessary.

32 8.590.2.F. Supplies shall be for a specific purpose, not incidental or general purpose usage.

33 8.590.2.G. The following DME and Supplies categories are benefits for members regardless of age,
34 and include but are not limited to:

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1 1. Ambulation devices and accessories including but not limited to canes, crutches or
2 walkers.

3 2. Bath and bedroom safety equipment.

4 3. Bath and bedroom equipment and accessories including, but not limited to, specialized
5 beds and mattress overlays.

6 4. Manual or power Wheelchairs and accessories.

7 5. Diabetic monitoring equipment and related disposable supplies.

8 6. Elastic supports/stockings.

9 7. Blood pressure, apnea, blood oxygen, pacemaker and uterine monitoring equipment and
10 supplies.

11 8. Oxygen and oxygen equipment in the member's home, a nursing facility or other
12 institution. The institutional oxygen benefit is fully described in 10 C.C.R. 2505-10,
13 Sections 8.580, and 8.585.

14 9. Transcutaneous and/or neuromuscular electrical nerve stimulators (TENS/NMES) and
15 related supplies.

16 10. Trapeze, traction and fracture frames.

17 11. Lymphedema pumps and compressors.

18 12. Specialized use rehabilitation equipment.

19 13. Oral and enteral formulas and supplies.

20 14. Parenteral equipment and supplies.

21 15. Environmental controls for a member living unattended if the controls are needed to
22 assure medical safety.

23 16. Facilitative Devices.

24 a. Telephone communication devices for the hearing impaired and other facilitative
25 listening devices, except hearing aids, and Cochlear Implants.

26 b. Computer equipment and reading devices with voice input or output, optical
27 scanners, talking software, Braille printers and other devices that provide access
28 to text.

29 c. Computer equipment with voice output, artificial larynges, voice amplification
30 devices and other alternative and augmentative communication devices.

31 d. Voice recognition computer equipment software and hardware and other forms of
32 computers for persons with disabilities.

33 e. Any other device that enables a person with a disability to communicate, see,
34 hear or maneuver including artificial limbs and orthopedic footwear.

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1 17. Complex Rehabilitation Technology.

2 8.590.2.H. The following DME are benefits to members under the age of 21:

3 1. Hearing aids and accessories.

4 2. Phonic ear.

5 3. Therapy balls for use in physical or occupational therapy treatment.

6 4. Selective therapeutic toys.

7 5. Computers and computer software when utilization is intended to meet medical rather
8 than educational needs.

9 6. Vision correction unrelated to eye surgery.

10 8.590.2.I. The following Prosthetic or Orthotic Devices are benefits for members regardless of age:

11 1. Artificial limbs.

12 2. Facial Prosthetics.

13 3. Ankle-foot/knee-ankle-foot orthotics.

14 4. Recumbent ankle positioning splints.

15 5. Thoracic-lumbar-sacral orthoses.

16 6. Lumbar-sacral orthoses.

17 7. Rigid and semi-rigid braces.

18 8. Therapeutic shoes.

19 9. Orthopedic footwear, including shoes, related modifications, inserts and heel/sole
20 replacements.

21 10. Specialized eating utensils and other medically necessary activities of daily living aids.

22 11. Augmentative communication devices and communication boards.

23 8.590.2.J. Repairs and replacement parts are covered under the following conditions:

24 1. The item was purchased by Medicaid; or

25 2. The item is owned by the member, member's family or guardian; and

26 3. The item is used exclusively by the member; and

27 4. The item's need for repair was not caused by member Misuse or Abuse; and

28 5. The item is no longer under the manufacturer warranty.

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8.590.2.K. The minimum replacement timeline for a Speech Generating Device is five years.

1. Stolen devices may be replaced within the five-year timeline; however, the client is limited to one-time replacement due to theft, and a police report must be provided for verification of the incident.

2. Replacement will not be granted within the five-year timeline for devices that are damaged, lost, misused, abused or neglected.

8.590.2.L. Repairs, replacement, and maintenance shall be:

1. Based on the manufacturer’s recommendations, and

2. Performed by a qualified rehabilitation professional, and

3. Allowed on the member’s primary equipment or one piece of backup equipment.

4. Multiple backup equipment will not be repaired, replaced or maintained.

8.590.2.M. If repairs are frequent and repair costs approach the purchase price of new equipment, the provider shall make a request for the purchase of new equipment. The prior authorization request shall include supporting documentation explaining the need for the replacement equipment and the cost estimates for repairs on both the old equipment and the new equipment purchase.

8.590.2.N. Supplies are a covered benefit when related to the following:

1. Surgical, wound or burn care.

2. Syringes or needles.

3. Bowel or bladder care.

4. Incontinence.

5. Antiseptics or solutions.

6. Gastric feeding sets and supplies.

7. Tracheostomy and endotracheal care supplies.

8. Diabetic monitoring.

8.590.2.O. Quantities of Supplies shall not exceed one month’s supply unless they are only available in larger quantities as packaged by the manufacturer.

8.590.2.P. Medicaid members for whom Wheelchairs, Wheelchair component parts and other specialized equipment were authorized and ordered prior to enrollment in a Managed Care Organization, but delivered after the Managed Care Organization enrollment shall be the responsibility of the Department. All other DME and Supplies for members enrolled in a Managed Care Organization shall be the responsibility of the Managed Care Organization.

8.590.2.Q. Items, for the purposes of Rule 8.590, that are used for the following are not a benefit to a member of any age:

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1 1. Routine personal hygiene.

2 2. Education.

3 3. Exercise.

4 4. Participation in sports.

5 5. Cosmetic purposes.

6 8.590.2.R. For members age 21 and over, the following items are not a benefit:

7 1. Hearing aids and accessories.

8 2. Phonic ears.

9 3. Therapeutic toys.

10 4. Vision correction unrelated to eye surgery.

11 8.590.2.S. Rental Policy.

12 1. The Department may set a financial cap on certain rental items. The monetary price for
13 those items shall be determined by the Department and noted in the fee schedule. The
14 provider is responsible for all maintenance and repairs as described at 8.590.4.N-P, until
15 the cap is reached.

16 2. Upon reaching the capped amount, the equipment shall be considered purchased and
17 shall become the property of the member. The provider shall give the member or
18 caregiver all applicable information regarding the equipment. The equipment shall not be
19 under warranty after the rental period ends.

20 3. The rental period may be interrupted, for a maximum of sixty consecutive days.

21 a. If the rental period is interrupted for a period greater than sixty consecutive days,
22 the rental period must begin again. The interruption must be justified,
23 documented by a physician, and maintained by the provider as described at 10
24 CCR 2505-10, Section 8.590.4.E.

25 4. If the member changes providers, the current rental cap remains in force.

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