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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 4-2023
CHAPTER 855
BOARD OF PHARMACY

FILED
02/10/2023 1:32 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporarily suspends statewide drug therapy management protocols for COVID-19 Monoclonal Antibody & COVID-19 Antiviral

EFFECTIVE DATE: 02/10/2023 THROUGH 08/08/2023

AGENCY APPROVED DATE: 02/10/2023

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NEED FOR THE RULE(S):

The Emergency Use Authorization (EUA) for each product has been updated. The updated EUA conditions now differ from the approved statewide drug therapy management protocols which requires their removal.
-COVID-19 Monoclonal Antibody- REGENCOV. EUA updated 1/24/2022. REGEN-COV (casirivimab and imdevimab) is not currently authorized in any U.S. region due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to REGEN-COV. Therefore, REGEN-COV may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the FDA.
-COVID-19 Antiviral- Paxlovid. EUA updated 2/1/2023. The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved PAXLOVID which includes nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate coronavirus disease 2019 (COVID-19) and who are at high risk for progression to severe COVID-19, including hospitalization or death.

JUSTIFICATION OF TEMPORARY FILING:

COVID-19 Monoclonal Antibody- REGENCOV. REGEN-COV (casirivimab and imdevimab) is not currently authorized in any U.S. region.
COVID-19 Antiviral- Paxlovid. Under Oregon state laws, pharmacists cannot diagnose. The current Paxlovid EUA requires a diagnosis to prescribe Paxlovid, which is not required in the Board's Paxlovid protocol (based on the EUA dated 10/27/2022) and appears to be preempted by federal law.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

REGENCOV EUA- https://www.fda.gov/media/145610/download; https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs https://www.fda.gov/media/145610/download
Paxlovid EUA- https://www.fda.gov/media/155050/download https://www.fda.gov/media/155050/download

Determination of Public Health Emergency https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency
Frequently Asked Questions on the Emergency Use Authorization for Paxlovid for Treatment of COVID-19- https://www.fda.gov/media/155052/download
Emergency Use Authorization of Medical Products and Related Authorities- https://www.fda.gov/media/97321/download

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AMEND: 855-020-0300

RULE SUMMARY: Temporary suspends statewide drug therapy management protocols for COVID-19 Monoclonal Antibody and COVID-19 Antiviral due to:
-COVID-19 Monoclonal Antibody- REGENCOV. REGEN-COV (casirivimab and imdevimab) is not currently authorized in any U.S. region.
-COVID-19 Antiviral- Paxlovid. Under Oregon state laws, pharmacists cannot diagnose. The current Paxlovid EUA requires a diagnosis to prescribe Paxlovid, which is not required in the Board's Paxlovid protocol (based on the EUA dated 10/27/2022) and appears to be preempted by federal law.

CHANGES TO RULE:

855-020-0300
Protocol Compendium
A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:¶
(1) Continuation of therapy (v. 06/2021)¶
(2) Conditions¶
(a) Cough and cold symptom management¶
(A) Pseudoephedrine (v. 06/2021);¶
(B) Benzonatate (v. 06/2021);¶
(C) Short-acting beta agonists (v. 06/2021);¶
(D) Intranasal corticosteroids (v. 06/2021);¶
(b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶
(c) COVID-19 ~~Monoclonal Antibody (mAb) (v. 12/2021); ¶~~
~~(d) COVID-19 Antigen Self-Test (v. 12/2021); ¶~~
~~(e) COVID-19 Antiviral (v. 12/2022).~~Antigen Self-Test (v. 12/2021); ¶
(3) Preventative care¶
(a) Emergency Contraception (v. 06/2021);¶
(b) Male and female condoms (v. 06/2021);¶
(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2022);¶
(d) Travel Medications (v. 12/2022);¶
(e) HIV Post-exposure Prophylaxis (PEP) (v. 12/2022);¶
(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 12/2022); and¶
(g) Contraception (v. 12/2022).¶
[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689