

OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 22-2021
CHAPTER 855
BOARD OF PHARMACY

FILED
09/01/2021 4:08 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Adds COVID-19 Monoclonal Antibody protocol to Protocol Compendia based on PHPFAC recommendation

EFFECTIVE DATE: 09/01/2021 THROUGH 02/27/2022

AGENCY APPROVED DATE: 08/31/2021

CONTACT: Rachel Melvin 800 NE Oregon St., Suite 150
971-673-0001 Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

Filed By:
Rachel Melvin
Rules Coordinator

v

NEED FOR THE RULE(S):

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule to address regulations impacting the health, safety and welfare of Oregonians. Due to the declared COVID-19 public health emergency there is a need to increase access to COVID-19 monoclonal antibody (mAb) therapy for the treatment and post-exposure prophylaxis of COVID-19.

JUSTIFICATION OF TEMPORARY FILING:

The COVID-19 delta variant continues to increase case numbers and hospitalizations in Oregon to the point that hospital capacity may soon be exceeded. To help reduce the need for hospitalization of high-risk persons who have or have been exposed to COVID-19, the Board of Pharmacy has adopted a statewide protocol for pharmacists to administer REGEN-COV™, which has been authorized for emergency use by the FDA for this purpose. Improving access to mAb therapy may decrease the number persons admitted to hospitals with COVID-19, will preserve hospital capacity and is in the interest of public health.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS 689.645 and 689.649 state that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC (Public Health and Pharmacy Formulary Advisory Committee); and adopted by rule of the Board. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify a patient's medical need, then prescribe and dispense a drug or device to the patient. <https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf> , <https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf> , https://www.oregon.gov/pharmacy/Documents/Draft_COVID_mAb_Protocol_Rulemaking.pdf

AMEND: 855-020-0300

RULE SUMMARY: This temporary emergency rule adopts a statewide drug therapy management protocol for treatment or post-exposure prevention of COVID-19 infection utilizing monoclonal antibody therapy.

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); and¶¶

(D) Intranasal corticosteroids (v. 06/2021)¶¶

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021)¶¶

(c) COVID-19 Monoclonal Antibody Protocol (v.08/2021)¶¶

(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 Protocol (v. 06/2021);¶¶

(d) Travel Medications Protocol (v. 06/2021) ¶¶

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 06/2021); and ¶¶

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 06/2021)¶¶

[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