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MEMORANDUM

TO: NYS Article 31 Mental Health Provider Agencies
NYS Article 28 Hospital Psychiatry Chiefs
OMH-Operated Psychiatric Center Executive Directors, Clinical Directors, Chief Nursing Officers, Pharmacists

FROM: Dr. Thomas Smith, Chief Medical Officer, NYS OMH

DATE: April 16, 2020

SUBJECT: Update: clozapine blood test monitoring recommendations

As noted in a prior communication, both the FDA and Clozapine REMS have confirmed that prescribers and pharmacies have discretion to order and dispense clozapine without an absolute neutrophil count (ANC) reported within the recommended timeframes. More recently, an international group of psychiatric researchers and clinicians issued a consensus statement and recommendations regarding use of clozapine.[1] The recommendations are:

1. The frequency of ANC reporting may be reduced to every 3 months, with dispensation of up to a 90-day supply (if it can be safely stored) for patients fulfilling all of the following criteria:
    - continuous clozapine treatment for > 1 year;
    - never had an ANC < 2000/μL (or < 1500/μL if history of benign ethnic neutropenia); and
    - no safe or practical access to ANC testing.

2. For patients on clozapine with any symptoms of infection (including those reported for severe acute respiratory syndrome coronavirus 2 [SARSCoV-2] such as cough, fever and chills, sore throat or other flu-like symptoms), an urgent physician assessment including a complete blood count (with ANC) should be obtained.

[1] Siskind et al, Consensus statement on the use of clozapine during the COVID-19 pandemic. J Psychiatry Neurosci. 2020 Apr 3;45(4):200061. doi: 10.1503/jpn.200061

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3. If patients on clozapine become symptomatic with fever and flu-like symptoms, the emergence of signs and symptoms of clozapine toxicity may require clinicians to reduce the dose of clozapine by as much as a half. Continue the lower dose until 3 days after the fever has subsided, then increase clozapine in a stepwise manner to the pre-fever dose.

NYS OMH endorses and suggests that prescribers follow these recommendations. Here is a suggested example of justification for a pharmacy prescription or inquiry from a pharmacist or representative from the Clozapine REMS registry:

“The patient’s latest ANC was XXXX on MM/DD/2020 and is entered into the Clozapine REMS registry. I am monitoring this patient’s ANC every 3 months and ordering a 90-day supply of clozapine as recommended by published expert consensus guidelines. The patient has received continuous clozapine treatment for over 1 year with stable ANCs.”

We hope this is helpful, please let us know if any questions.

CC:

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