

Instructions

1. Complete Section 1 below to ensure the Knowledge Assessment is associated with your program record.
2. Answer all questions in Section 2.
3. Fax the completed *Knowledge Assessment for Prescribers* to the Clozapine REMS at **800-878-5927**.

For real-time processing of this Knowledge Assessment, please go to www.clozapinerems.com.

1 Prescriber Information (PLEASE TYPE OR PRINT)

First Name:	MI (opt):	Last Name:
Individual NPI #:	Individual DEA #:	
Email Address:		
Clinic/Practice Name:		
Address:		
City:	State:	Zip Code:
Phone:	Ext. (opt):	Fax (opt.):

2 Knowledge Assessment

Please select the best answer for each of the following questions. All questions must be answered correctly to become certified.

Question 1

All clozapine products are only available under the single shared Clozapine REMS.

- A. True
- B. False

Question 2

Clozapine is associated with severe neutropenia, which can lead to serious infection and death.

- A. True
- B. False

Question 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L
- C. An absolute neutrophil count (ANC) less than 500/ μ L
- D. None of the above

Question 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ μ L for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ μ L for a patient who is part of the general population (i.e., the patient does not have documented BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

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Question 5

Before clozapine treatment initiation, a certified prescriber must:

- A. Determine if the patient has documented BEN
- B. Enroll the patient in the Clozapine REMS
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and submit it to the Clozapine REMS
- F. All of the above

Question 6

In the outpatient setting, prescribers must submit the *Patient Status Form* monthly, to the single shared Clozapine REMS, before the patient can be dispensed clozapine.

- A. True
- B. False

Question 7

How much clozapine can be dispensed?

- A. A 30-day supply
- B. A 90-day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is, according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

Question 8

Regarding patients with documented BEN, which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

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Question 9

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

Question 10

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC $\geq 1500/\mu\text{L}$ if the patient is part of the general population (i.e., if the patient does not have documented BEN)
- B. Mild neutropenia is within the normal range for a patient with documented BEN
- C. If the patient has documented BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

Question 11

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the general population or has documented BEN
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt therapy and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the general population or has BEN
- D. None of the above

Question 12

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the general population or has BEN and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the general population (i.e., if the patient does not have documented BEN), interrupt treatment and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

Required for all prescribers	Prescriber Signature <div style="font-size: 2em; font-weight: bold; margin-left: 10px;">X</div>	Date: <div style="text-align: center; font-size: 1.5em;">/ /</div>
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