

**Instructions**

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

For real-time processing of this Knowledge Assessment, please go to [www.clozapinerems.com](http://www.clozapinerems.com).

**1 Pharmacy Information** (PLEASE TYPE OR PRINT)

<b>Pharmacy Name:</b>		<b>Organization NPI #:</b>
<b>Address:</b>		
<b>City:</b>	<b>State:</b>	<b>Zip Code:</b>
<b>Phone:</b>	<b>Ext. (opt):</b>	<b>Fax (opt.):</b>

**2 Pharmacy Authorized Representative Information**

<b>First Name:</b>	<b>MI (opt):</b>	<b>Last Name:</b>
<b>Email Address:</b>		
<b>Phone:</b>	<b>Ext. (opt):</b>	<b>Fax (opt.):</b>

**3 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/ $\mu$ L
- B. An absolute neutrophil count (ANC) less than 1000/ $\mu$ L
- C. An absolute neutrophil count (ANC) less than 500/ $\mu$ L
- D. None of the above

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**Question 4****Before initiating treatment with clozapine:**

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ $\mu$ L for a patient with documented benign ethnic neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ $\mu$ 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

**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**

**Prescribers must submit the *Patient Status Form* monthly, to the Clozapine REMS, before the patient is authorized to be dispensed clozapine.**

- A. True
- B. False

**Question 7****Before each outpatient dispensing or before the first inpatient dispensing for a patient, the pharmacist must:**

- A. Verify the patient is enrolled in the Clozapine REMS
- B. Verify the patient is authorized to receive drug
- C. Obtain a REMS Dispense Authorization each time from the REMS
- D. For patients enrolled but not authorized by the Clozapine REMS to receive clozapine, document and submit an available, current ANC that is within acceptable range and obtain a Dispense Rationale
- E. All of the above

**Question 8****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

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**Question 9**

**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

**Question 10**

**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 11**

**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  $ANC \geq 1500/\mu L$  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 12**

**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  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$ ; 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

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**Question 13**

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	<b>Signature</b>	<b>Date:</b>
	<b>X</b>	/ /