

Figure 1. Resuming Monitoring Frequency after Interuption in Therapy.

WEEKLY, EVERY OTHER WEEK (BI-WEEKLY) AND EVERY 4 WEEKS (MONTHLY) MONITORING AND ELIGIBILITY

On May 12, 2005, the Food and Drug Administration (FDA) approved changes to Clozaril labeling allowing certain qualified patients, under specific conditions to undergo monthly (every 4 weeks) monitoring. The revised labeling states that patients initiated on Clozaril must have a baseline White Blood Cell (WBC) count and baseline Absolute Neutrophil Count (ANC) before initiation of treatment. The WBC must be at least 3500/mm³ and the ANC must be at least 2000/mm³ for initiation of therapy. During the first 6 months of therapy, patient must be monitored on a weekly basis. If acceptable WBC and ANC values (WBC ≥ 3500/mm³ and ANC ≥ 2000/mm³) have been maintained during the first 6 months of continuous therapy, the frequency of monitoring WBC and ANC values may be reduced to every other week (biweekly). After 6 months of every other week monitoring without interruption due to leukopenia, the frequency of monitoring WBC and ANC may be reduced to every 4 weeks (monthly).

WBC and ANC values must continue to be monitored <u>weekly</u> for at least 4 weeks after the discontinuation of Clozapine regardless of monitoring frequency at the time of discontinuation.

^{*}Transitions to reduce frequency of monitoring only permitted if all WBC \geq 3500 and ANC \geq 2000.