

	MEDICAL ASSISTANCE BULLETIN COMMONWEALTH OF PENNSYLVANIA * DEPARTMENT OF PUBLIC WELFARE	
	SUBJECT Clozapine Support Services	BY  Robert S. Zimmerman, Jr., M.P.H. Deputy Secretary for Medical Assistance Programs
NUMBER:	01-98-19, 29-98-08, 33-98-08	
ISSUE DATE:	December 29, 1998	
EFFECTIVE DATE:	February 1, 1992	

PURPOSE:

The purpose of this bulletin is to reissue the billing procedures for clozapine support services provided to eligible patients receiving clozapine (Clorazil). The billing procedures were previously published in Medical Assistance Bulletin 01-92-04, 29-92-02, 33-92-02.

SCOPE:

This bulletin applies to all psychiatrists, outpatient psychiatric clinics, and psychiatric partial hospitalization facilities enrolled in the Medical Assistance Program.

BACKGROUND:

Clozapine (brand name Clorazil) is an atypical antipsychotic drug used in the treatment of serious, persistent and intractable Schizophrenia. The Department pays for all medical monitoring services related to clozapine therapy such as the medication, physician office visits, clinic visits, laboratory services, and clozapine monitoring and evaluation visits. Monitoring and evaluation visits are limited to five visits per patient per calendar month, and only outpatient psychiatric clinics may bill for this service.

In addition to the comprehensive coverage, the Department realizes that some patients on clozapine therapy will require additional support services to ensure safe medical management of the drug therapy.

DISCUSSION:

The Department developed these services and corresponding procedure codes in order for psychiatrists, outpatient psychiatric clinics, and psychiatric partial hospitalization facilities to provide and bill for clozapine support services.

DEFINITIONS:

Clozapine support services must be ordered and directed by a psychiatrist who determines they are medically necessary for a person with a diagnosis of Schizophrenia to receive clozapine on an outpatient basis. These services are a group of discrete patient medical care functions performed by a psychiatrist, or under the direction and supervision of a psychiatrist by a pharmacist, registered nurse, or physician assistant. The services must include at least one face-to-face encounter with the patient each week. The support services are intended to assure collaborative, uninterrupted, and safe patient medical management.

Schizophrenia is a major mental disorder, usually of psychotic proportion, characterized by disturbances of thought, behavior, and mood. Thought disturbances are marked by alterations of concept formation that may lead to misinterpretation of reality and sometimes to delusions and hallucinations. Mood changes include ambivalence, constriction, inappropriateness and loss of empathy with others. Behavior may be withdrawn, regressive, and bizarre. The recognized subtypes are disorganized (295.1x), catatonic (295.2x), paranoid (295.3x), residual (295.6x) and undifferentiated (295.9x).

COVERED SERVICES:

Clozapine support services include the following and can be performed by a psychiatrist, or a pharmacist, registered nurse or

physician assistant under the direction and supervision of a psychiatrist:

1. Providing or arranging emergency coverage 24 hours per day, seven days per week, in order to assure prompt response to any adverse physical side effects experienced by the patient (e.g., seizure, signs of immune system suppression).
2. Coordinating medical monitoring and clinical management services among the patient, psychiatrist, pharmacist, and laboratory.
3. Scheduling, supervising, or performing at least a weekly phlebotomy for white blood count (WBC) or a complete blood count (CBC) laboratory analysis throughout the duration of therapy and for not less than four weeks or more than eight weeks from the date of drug discontinuation.
4. Contingency capacity to obtain weekly or more frequent blood specimens from the patient through a scheduled or unscheduled visit to the patient's place of residence.
5. Delivering or arranging for transport of blood specimens to an approved laboratory services provider.
6. Receiving and checking laboratory reports for values within the range specified by the psychiatrist and communicating the test results and any change in WBC or CBC trend to the psychiatrist or pharmacist. Test results within a normal range must be reported within 48 hours of receipt to the psychiatrist; **abnormal results must be communicated to the psychiatrist immediately.**
7. Carrying out psychiatrists orders for redraws resulting from any abnormal WBC or CBC values, or as ordered by the psychiatrist based upon the frequency of WBC or CBC monitoring warranted by the patient's condition.
8. Assessing and communicating to the psychiatrist the laboratory/physical/behavioral status of the patient at least weekly.
9. Obtaining and recording individual patient information (e.g., temperature, pulse, and respiration weekly during initial drug titration and once a month thereafter; all side effects observed or reported; laboratory values; patient medication compliance concerns/problems; prescription orders; and visit summaries) in the patient's record maintained at a location designated by the psychiatrist or provider agency.
10. Assisting in planning patient travel/relocation to facilitate continuity in weekly blood and adverse side effects monitoring.
11. Arranging or conducting patient education about the drug, as well as family education.

NON-COVERED SERVICES:

Payment will be not be made for the following types of services:

1. Services that the psychiatrist determines are not medically necessary.
2. Services that are not ordered by a licensed psychiatrist.
3. Services provided to an eligible recipient during an inpatient hospital or nursing home stay excluding the day of admission or discharge.
4. Home visits for services other than those required for drug monitoring.
5. Services provided beyond the eligibility time limits.
6. Clozapine support services prescribed for the treatment of mental illness other than Schizophrenia.

ELIGIBLE RECIPIENTS:

Categorically needy, medically needy, and State Blind Pension recipients are eligible to receive clozapine support services. Eligible recipients may receive these services for the period of time that the psychiatrist determines is medically necessary, but not to exceed six consecutive calendar months.

If the psychiatrist determines that clozapine support services continue to be medically necessary at the end of a six month eligibility period, the psychiatrist may reorder a new eligibility period. The maximum time period for each order shall not exceed six consecutive calendar months.

The psychiatrist's original assessment and all reassessments of the person receiving clozapine must document the ongoing efficacy of the drug in treating the patient's Schizophrenia and the medical necessity for the support services.

If a patient is discontinued from clozapine therapy, the patient remains eligible for clozapine support services on an outpatient basis for not less than four weeks or more than eight weeks after the drug therapy is stopped.

MEDICAL NECESSITY CRITERIA:

The criteria which clinically support the decision of medical necessity are as follows:

1. The patient is age 16 or over, has a primary diagnosis of Schizophrenia, meets the indications for treatment delineated in Mental Health Bulletin #SMH-91-01 or its successor; and
2. A psychiatrist received authorization from the drug company's national registry for use of the drug with the patient; and
3. The patient accepts an initial clozapine trial on an outpatient basis; or
4. The patient accepts the start of an outpatient rechallenge of clozapine after any period of discontinuation regardless of length or reason for discontinuation; or
5. The patient accepts continuity of medical monitoring when clozapine therapy is a requirement for discharge from the inpatient status; or
6. The patient receiving clozapine on an outpatient basis demonstrates insufficient judgement or independence of functioning to satisfy medical monitoring requirements essential for continued access to and safe management of clozapine therapy; or
7. The patient has a history of non-compliance with after care plans; or
8. The patient's medical condition requires active monitoring due to the presence of other complicating physical conditions and treatment for the same; or
9. The patient presents an improved quality of life but an inadequate or incomplete behavioral response to clozapine therapy based upon the psychiatrist's judgement and/or as substantiated through the administration of standardized behavioral assessment (e.g., Brief Psychiatric Rating Scale, Nursing Observation Scale or Negative Symptoms Assessment Scale).

In certain circumstances, a psychiatrist may prescribe this service for an outpatient who does not fully meet the medical necessity criteria. In this instance, the psychiatrist must document the reason(s) for deviation from the eligibility criteria as well as concurrence from another psychiatrist.

PAYMENT:

The Department will reimburse psychiatrists, outpatient psychiatric clinics, or psychiatric partial hospitalization facilities for medically necessary clozapine support services provided to eligible recipients. Payment is made for medically necessary clozapine support services based upon a flat weekly reimbursement rate, regardless of the frequency or intensity of monitoring activities during each seven day calendar period.

The types of service, procedure codes, terminologies, and corresponding fees for psychiatrists, psychiatric clinics, and partial hospitalization facilities are as follows:

<u>Provider Type</u>	<u>Type of Service</u>	<u>Procedure Code</u>	<u>Terminology</u>	<u>Fee</u>
01 Psychiatrist	70	W1857	Clozapine Support Services	\$30.00
29 Outpatient Psychiatric Clinic	70	W1858	Clozapine Support Services	\$30.00
33 Partial Hospitalization Facility	AH	W1859	Clozapine Support Services	\$30.00

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free telephone number for your provider type.

Visit the Office of Medical Assistance Programs website at www.dpw.state.pa.us/omap.