Piedmont WellStar HealthPlans, Inc.
DEPRESSION CLINICAL GUIDELINE

Relevance to Population:
Major depression is a serious medical illness affecting 15 million American adults or approximately 5-8% of the adult population in a given year. An estimated 1 in 10 U.S. adults report current depression, either meeting criteria for major depression or other types of depression accompanied by disturbances in mood, energy, and loss of interest in usual activities.[i] Among all medical illnesses, major depression is the leading cause of disability in the United States as well as globally.[ii] This disorder often disrupts an individual's work, family, and personal life. Its impact is often severe, and can be fatal. Depression can strike alone or in combination with other diseases. Depression is often found in patients with illnesses such as diabetes, cancer, asthma, cardiovascular disease, and obesity disease can negatively affect the course and outcome of such chronic conditions.
If left untreated, depression can increase both morbidity and mortality rates. Research demonstrates that depression is highly treatable. The vast majority of people seeking treatment for depression significantly improve.

Population Covered by Guideline:
All members aged 18 and older who are diagnosed with or who are at risk for developing a major depressive disorder.

Clinical Indicators Measured by Piedmont WellStar HealthPlans, Inc.:
The percentage of members 18 years of age and older who were diagnosed with a new episode of major depression and treated with antidepressant medication, and who remained on an antidepressant medication treatment. Two rates are reported. HEDIS®

- Effective Acute Phase Treatment: The percentage of newly diagnosed and treated members who remained on an antidepressant medication for at least 84 days (12 weeks). HEDIS®
- Effective Continuation Phase Treatment: The percentage of newly diagnosed and treated members who remained on an antidepressant medication for at least 180 days (6 months). HEDIS®

Importance of Screening for Depression in the Primary Care Setting:
Depression often is not recognized or treated, and the cost is staggering. Patients may not present initially with a complaint of depressed mood though the clinician may suspect major depression in the presence of multiple medical visits, multiple unexplained symptoms, work or relationship dysfunction, poor follow through with recommendations, fatigue, sleep problems, cognitive problems, irritable bowel syndrome, complaints of stress .[iii] There is a high risk of comorbid depression in patients with substance abuse, diabetes, cardiovascular disease and chronic pain and individuals with such conditions should be screened for depression.

The negative impact of post- partum depression on women and their children has been widely recognized. The available evidence suggests that the prevalence of depression in postpartum women mirrors that in other women of reproductive age. There remains uncertainty about the target for screening (major depression or other types as well) and which is the best screening instrument. Most studies have found low rates of follow up with perinatal depression with the best outcome when screening, diagnostic, and treatment services were all accessible within the same primary care setting.[iv]

Depression screening tools can be used to identify members suffering from depression. Screening can easily be incorporated into preventive health care visits for all adults. It is suggested that physicians or other qualified health care professionals routinely ask the following two questions (PHQ-2):

- Over the last two weeks how often have you been bothered by feeling down, depressed, or
- hopeless? Over the last two weeks how often have you been bothered by little interest or pleasure in doing things?

In the event that the patient responds affirmatively to either or both questions, a more thorough evaluation should be completed. Use of a validated screening tool, such as the Patient Health Questionnaire (PHQ-9), can further aid in recognition. This tool can be found in the MacArthur Depression Toolkit at http://www.depression-primarycare.org/. The PHQ-9 is especially useful as it takes only a few minutes to complete, can be self-administered, is easily repeatable to track progress, and incorporates the 9 criteria listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM5) which are to be considered in making a diagnosis of major depression. Five or more of the following symptoms must be present during the same two week period, represent a change from previous functioning and at least one of the symptoms is either depressed mood or loss of interest or pleasure[v].

- depressed mood
- loss of interest or pleasure in nearly all activities
- weight loss/gain
- insomnia/hypersomnia
- psychomotor retardation/ agitation
- fatigue/loss of energy
- worthlessness/guilt
- impaired concentration
- thoughts of death/suicide

The symptoms must cause significant distress or impaired functioning and are not attributable to the physiologic effects of a substance or another medical disorder.
Assessment should include symptoms of:

- Bipolar disorder.
- Mood disorder due to general medical condition (e.g. stroke, cancer, HIV/AIDS, Parkinson's, dementia, multiple sclerosis, thyroid, etc.)
- Psychotic symptoms

Suicidality Assessment
Assessment of suicide potential is an essential part of the evaluation for clinical depression. Evaluation should include:

- Assess suicide risk factors: hopelessness, general medical illnesses, family history of substance abuse and or/suicide, psychotic symptoms, living alone or lack of social support, prior suicide attempts or agitated
- depression
- Ask directly about the content and frequency of suicidal ideation, intent and plans
- Protective factors- those that would decrease the chance of member making an attempt Access to means of suicide and lethality of those means

If the assessment indicates any significant degree of suicidal risk, then immediate arrangements for psychiatric assessment for the appropriate level of care.

Available Treatment Options for Depression in the Primary Care Setting:

- Watchful waiting with supportive guidance (mild depression only)
- Psychotherapy (Use an evidenced-based model; a depression-focused psychotherapy alone can be considered as an initial treatment choice alone for mild to moderate depressive disorder).
- Psychopharmacology- moderate to severe depression (typically Major Depression)
- Psychopharmacology plus Psychotherapy- may be particularly helpful for complicated, chronic presentations or if partial responderECT- is reserved for highly selected patients after psychiatric consultation.
- Consider hospitalization if suicidal ideation is present
- The clinician selects the treatment modality based upon the diagnosis, severity of illness, patient preference, and monitoring of treatment response. Referral for a psychiatric evaluation is also an option.

Effective Management of Antidepressant Medications:

ACUTE PHASE
TREATMENT — AIM TO REDUCE AND ELIMINATE DEPRESSIVE SYMPTOMS AND RETURN FUNCTIONING

Expected Response:
4 – 8 week trial — 50% reduction in symptoms. Recommend the use of standardized self-reports of symptom severity and adverse effects to be given to patient at every visit to help the clinician quantify the benefit of the antidepressant medication. If after another 4-8 weeks treatment there is minimal or no response, then consider optimizing the dose of medication, augmentation with depression focused psychotherapy, other agents, and change to another non MAO antidepressant.

10 - 12 week trial — nearly 100% reduction in symptoms.

Treatment Strategy

- The initial goal should be to achieve a targeted dose (in the upper range of FDA recommendations for antidepressant medications) by week 6 and monitor progress for another 6 weeks. Thus a trial should be 12 weeks in duration
- *Every 1 - 2 weeks,* monitor patient compliance and symptoms.
- Selection of antidepressant is based on patient preference, anticipated side effect profile (sedating, activating, weight gain, impact on sex life; anticholinergic side effects), safety and tolerability, co-occurring conditions, potential drug interactions, half-life, cost [vi]
- Side effects are often responsible for discontinuing medication prematurely. Strategies for management of side effects include acknowledge patient's complaints, supportive waiting as some side effects subside within 2 weeks' temporarily lower the dose, treat side effects, consider change to different antidepressant
- If partial response/remission, the antidepressant medication trial should be continued for another 6 weeks.
- If *no response by 6 weeks* — increase dose or switch drugs and/or add psychotherapy.
- If *no response by 12 weeks* — increase dose or switch drugs and/or consult a behavioral health specialist.

CONTINUATION PHASE OF TREATMENT — AIM TO PREVENT RELAPSE IN THE VULNERABLE PERIOD FOLLOWING REMISSION (commonly in first 6 months).

Patient Having an Initial Episode of Depression:
Treatment Strategy
Continue antidepressant medication for *4 – 9 months* to prevent relapse. In general the dose in continuation phase is same as in acute phase. To prevent relapse in continuation phase, depression focused psychotherapy recommended (best evidence is for cognitive behavioral therapy CBT).

MAINTENANCE PHASE- AIM TO PROTECT HIGH RISK PATIENTS AGAINST RECURRENCE
Patient Having Recurrent Episodes of Depression:
Three or more prior major depressive episodes or patient with chronic major depressive disorder

Treatment Strategy
Continue antidepressant medication for *at least 12 months* using similar dosage as prescribed in acute phase.

1. Initially, the patient should be evaluated every one to two weeks to monitor patient compliance, symptom improvement, and medication side effects.
2. The patient should have at least a partial response (50% reduction in symptoms) by 6 weeks and remission by 10-12 weeks.
3. The medication dose should be increased (or, if this is ineffective, the antidepressant should be changed) if there is not a partial response by 6 weeks or remission by 10-12 weeks.
4. The antidepressant should be continued at least six months after depressive symptoms have remitted.
5. Patients who have two or more episodes of major depression in a five-year period may be considered for maintenance antidepressant therapy.
6. Psychological counseling may be used alone (if the patient prefers this to medications) in cases of mild to moderate depression. As with antidepressants, the patient should have at least a partial response by 6 weeks and remission by 10- 12 weeks.
7. In more severe depression, psychological counseling should only be used in conjunction with antidepressants. In some patients such adjunctive psychological counseling may prevent subsequent relapses and recurrences once treatment with antidepressant ends.

Treating Depression in the Primary Care Setting:
Approximately one out of every two members newly diagnosed with depression is in the sole care of their PCP. If you elect to provide pharmacotherapy for members with depressive symptoms, please arrange for at least 3 follow-up visits in the first 12 weeks of treatment. One of these visits should be with the prescribing practitioner to adequately evaluate clinical response, side effect profile, and compliance. Behavioral health practitioners can share valuable observations for the other visits if you deem this appropriate. Coordination of care is critical to treatment success. Two-way communication among clinicians treating the same patient is essential to quality care. In managing patients who are prescribed antidepressant medications, clinical guidelines suggest to:

- Begin the medication trial following the manufacturer's recommended doses. Selective serotonin reuptake inhibitors (SSRIs) are typically first choice. Use a single agent unless patients fail several trials of individual agents (i.e., three trials at full dosage for adequate length of time).
- Assess the effects of the medications frequently and adjust to a therapeutic level not to exceed the highest recommended dose**.**
- Switch to another antidepressant medication if the response is not satisfactory in six weeks at maximum recommended dosages. Avoid polypharmacy.
- Be aware of medication interactions with antidepressants (especially those with P450 metabolism).

- Remember elderly patients are at higher risk for significant side effects or drug interactions; consider lowest possible dose and slow titration.
- Ensure length of medication trial is adequate. For patients suffering from a single depressive episode, continue the antidepressant for at least six months after depressive symptoms have remitted. This strategy diminishes the risk of relapse. For patients with two or more episodes of depression, continue antidepressant medication for at least one year or consider ongoing treatment indefinitely at an effective dose — typically at the same dosage used in the acute phase of the illness. Maintaining patients with a history of depression on an antidepressant medication over the long term has been found to not only reduce the likelihood of recurrence but also to reduce the severity of symptoms that are suffered if a relapse should occur.
- Medication should not be abruptly discontinued. Taper after providing education about relapse prevention.

For patients with mild depression, watchful waiting is often a highly effective strategy. Patients often can benefit from this approach provided the clinician offers support, encourages positive coping skills, and prompts behavioral changes such as increasing pleasurable activities and exercise.

Additional practitioner resource information to aid in the detection and treatment of depression in the primary care setting is available from the Institute for Clinical Systems Improvement (ICSI) Guideline, Major Depression in Adults in Primary Care https://www.icsi.org/_asset/fnhdm3/Depr-Interactive0512b.pdf (Updated May 2012).

Who needs behavioral health specialty care?

Physicians are encouraged to refer patients to a behavioral health practitioner if the patients have:

- Severe psychiatric disorders, for example, depression with psychotic features or
- mania History of mania
- Treatment-resistant disorders, i.e., depression not responsive to one or two adequate psychotropic medication
- trials Risk of lethality
- Severe impairment in daily functioning
- A need for a combination of psychotropic medications
- Alcohol or substance abuse
- A complicated or uncertain
- diagnosis Complex social situation
- A need for psychiatric inpatient admission
- A need for psychotherapy; this service can be utilized in combination with the PCP following a
- patient on an antidepressant.

Referrals should also be made if the primary physician is not comfortable managing the patient's depression. Finally, patients hospitalized for major depression should be seen by a behavioral health specialist within seven days of discharge.

Collaboration and Coordination of Care:
Other health care professionals in addition to primary care provider, including behavioral health providers may be involved in the patient's overall treatment. It is important that care is coordinated, clinical information (with appropriate release of information) relevant to treatment is shared, and treatments are coordinated.

Additional Resources for Piedmont WellStar HealthPlans, Inc. patients

- ***My*Health Advice Line** is staffed by experienced Registered Nurses and is available 24/7 to provide telephone support to members. Call 855-514-3679.

- Online interactive preventive health programs and resources are available in partnership with WebMD by logging in at www.pwplans.org/individuals.

Member Educational Materials:
Recovery is often more successful when patients are active participants in treatment efforts. Educating patients about depression, its treatment, and especially steps they can take to get well can greatly aid in the recovery process. Excellent patient educational materials can be found at:

Adults
http://www.nami.org/ National Alliance on Mental Illness website.

http://www.DBSAlliance.org Depression and Bipolar Support Alliance website.

http://www.psychiatry.org/mental-health/key-topics/depression American Psychiatric Association website

http://www.mentalhealthamerica.net/go/depression Mental Health America website

Elderly
http://nihseniorhealth.gov/depression/toc.html NIH Senior Health

References:

[i] http://www.cdc.gov/features/depression.

[ii] WHO Depression Fact sheet N 360, October 2012, http://www.who.int/mediacentre/factsheets/fs369/en/

[iii] Trangle M, Dieperink B, Gabert T et al. Institute for Clinical Systems Improvement. Major Depression in Adults in Primary Care. http://bit.ly/Depr0512. Updated May 2012.

[iv] Effective Health Care Program, Efficacy and Safety of screening for Postpartum Depression for Postpartum Depression, Comparative Effectiveness Review, Number 106. www.effectivehealthcare.ahrq.gov/reports/final.cfm (accessed 07.05.13).

[v] American Psychiatric Association: Desk Reference to the Diagnostic Criteria from DSM5. Arlington, VA, American Psychiatric Association, 2013.

[vi] American Psychiatric Association. Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition, October 2012.