



MAJOR DEPRESSIVE DISORDER (ADULTS)

Behavioral
Clinical Practice Guidelines 2010
Health
Providers



MEDICAL MUTUAL OF OHIO®
AND ITS FAMILY OF COMPANIES



MAJOR DEPRESSIVE DISORDER (ADULTS)

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INTRODUCTION

The 2010 Behavioral Health Provider Clinical Practice Guidelines for Major Depressive Disorder (MDD) in Adults are not intended to represent a standard of medical care, but rather to serve as general guidelines for patient care. Diagnostic and management decisions are rightfully made by the treating clinician, in partnership with the patient, taking into account all available clinical information. Providing definitive clinical standards represents a virtually impossible task, and therefore, considerable reliance upon the clinical judgment and expertise of the treating clinician remains most prudent.

These guidelines summarize many somatic and psychological therapeutic modalities that are available in the treatment of adults with Major Depressive Disorder. These guidelines presume that a diagnosis of Major Depressive Disorder using DSM-IV-TR criteria has been established, and that substance abuse or dependence, as well as other medical factors that could complicate the treatment of Major Depressive Disorder have already been considered.

These recommendations are for your information only. These are not intended to be, and should not serve as, an exclusive course of treatment or a substitute for professional medical advice, diagnosis or treatment. Decisions regarding care are subject to individual consideration and should be made by the patient in concert with the treating medical professionals. The information does not establish or imply coverage for any particular treatment or service. The recommended services may not be covered. Eligibility and coverage depend upon the specific terms and conditions of the applicable benefit plan.

DISEASE DEFINITION AND CLINICAL CHARACTERISTICS

DSM-IV-TR Criteria

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) clinical criteria for a diagnosis of Major Depressive Disorder require that an individual must have a clinical course, which is characterized by at least one major depressive episode in the absence of a history of manic, mixed or hypomanic episodes. An essential feature of a major depressive episode is a period of at least two weeks during which there is either a depressed mood or the loss of interest or pleasure in nearly all activities.

Episodes of Substance-Induced Mood Disorder or Mood Disorder Due to a General Medical Condition do not constitute a diagnosis of Major Depressive Disorder. Additionally, the major depressive episode must not be more suitably accounted for by a Schizoaffective Disorder, and the episode must not be superimposed upon Schizophrenia, Schizophreniform Disorder, Delusional Disorder or Psychotic Disorder not otherwise specified.

Major Depressive Episode

Five (or more) of the following symptoms must be present during the same two-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly due to a general medical condition or mood-incongruent delusions or hallucinations.

- Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
Note: Can be irritable mood, especially in children and adolescents.
- Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others).
- Significant weight loss when not dieting or weight gain (e.g., a change of more than 5 percent of body weight in a month), or decrease or increase in appetite nearly every day.
Note: In children, consider failure to make expected weight gains.
- Insomnia or hypersomnia nearly every day.
- Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down).
- Fatigue or loss of energy nearly every day.
- Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick).
- Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others).
- Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

The symptoms do not meet criteria for a Mixed Episode (see DSM-IV-TR).

The symptoms cause clinically significant distress or impairment in social, occupational or other important areas of functioning.

The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than two months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms or psychomotor retardation.

Specific Features of Diagnosis

Severity

An episode of Major Depressive Disorder should be classified as mild, moderate or severe. Mild episodes are characterized by little in the way of symptoms beyond the minimum necessary to make a diagnosis. Moderate episodes have a few additional symptoms in excess of the minimum requirement. Severe episodes are characterized by the existence of several symptoms in excess of the minimum requirement and by the symptoms' significant interference with social and/or occupational functioning.

Melancholia

The melancholic subtype is a severe form of major depression with characteristic somatic symptoms. This subtype is believed to be particularly responsive to pharmacotherapy and electroconvulsive therapy.

Psychotic Features

Major Depressive Disorder may be accompanied by hallucinations and/or delusions, which may be congruent or incongruent with the depressive mood.

Other DSM-IV-TR Unipolar Depressive Disorders

Dysthymic Disorder

The differential diagnosis of Dysthymic Disorder and Major Depressive Disorder may be particularly confusing. The two disorders have similar symptoms and differ primarily in duration and severity. Major Depressive Disorder usually consists of one or more discrete major depressive episodes, which can be distinguished from the person's usual functioning. Dysthymic Disorder is characterized by a chronic mild syndrome with duration of at least two years and can only be diagnosed with at least a six-month remission after the diagnosis of Major Depressive Disorder.

Depressive Disorder Not Otherwise Specified

The Depressive Disorders Not Otherwise Specified category includes disorders with depressive features that do not meet the criteria for Major Depressive Disorder, Dysthymic Disorder, Adjustment Disorder with Depressed Mood or Adjustment Disorder with Mixed Anxiety and Depressed Mood. An example of Depressed Disorder Not Otherwise Specified includes Premenstrual Dysphoric Disorder.

The use of standardized self-reporting tools is recommended to help establish the diagnosis, pre-treatment baseline and measure treatment progress.

Natural History and Course

Although the average age of onset for Major Depressive Disorder is in the late twenties, the disorder can begin at any age. Symptoms usually appear over a period of days or weeks and may be insidious, but can occur very suddenly. Prodromal symptoms that do not meet diagnostic criteria may develop over several months. The duration of an episode of Major Depressive Disorder is variable, with untreated episodes typically lasting six months or longer. Some people may develop a manic or hypomanic episode, leading to a diagnosis of Bipolar Disorder.

The most serious complication of depression is suicidal behavior. In rare cases, if untreated, depression may result in violent acts against others.

Approximately 50 percent of the individuals who experience one episode of major depression will eventually have another episode. In some people, bouts of major depression may be separated by many years of excellent mental health. Others may experience clusters of recurrences, chronic residual symptoms or increasingly frequent periods of decompensation. A seasonal pattern of depression may occur and is characterized by a consistent temporal relationship between the onset and remission of symptoms and particular time periods of the year. Depression may also be associated with specific chronic medical diseases, comorbid psychiatric conditions, hormonal changes and certain pharmacotherapies.

TREATMENT PRINCIPLES

General Considerations

The treatment of Major Depressive Disorder requires a thorough assessment of the patient's symptoms and presenting clinical picture. Before any therapy can be initiated, the presence of coexisting medical conditions and/or substance use/abuse disorders must be explored. In addition to behavioral health factors, a medical evaluation of the patient is also necessary to detect any underlying medical illnesses that may contribute to, or precipitate, the depressive state.

Recommendations

Treatment of Major Depressive Disorder progresses through three phases: Acute, Continuation and Maintenance. The goal of treatment during the Acute Phase is remission of symptoms. The primary focus of the Continuation Phase is to identify and support those factors necessary to preserve remission. The goal of the Maintenance Phase is to assist susceptible patients in preventing a recurrence of their symptoms and to avoid additional major depressive episodes.

Treatment Options

There is an array of options for the treatment of Major Depressive Disorder. Options that may be used alone or in combination include a variety of psychotherapeutic modalities, antidepressant medications, electroconvulsive therapy and other approaches (e.g., light therapy). The Behavioral Health Practitioner must determine the most medically appropriate treatment plan and least restrictive setting to enhance recovery. Current research indicates that first-line therapy includes a combination of psychotherapy and antidepressant medication for moderate to severe depression and improves treatment outcomes.

Psychotherapy

There is a broad range of medically appropriate psychotherapies that may be useful in the treatment of Major Depressive Disorder. Generally, clinicians vary the approach to treatment based upon the patient's clinical presentation and particular circumstances. Factors that influence psychotherapeutic choices include clinician expertise, clinical experience, level of conflict or changes in an individual's life and the severity of the depressive episode.

The frequency of visits is determined by the amount of clinical contact needed by a patient as well as other management factors, such as the need to help ensure medication compliance and to manage suicide risk. The frequency of visits may vary throughout the course of treatment as indicated.

Psychotherapy, as the sole therapeutic intervention, may be employed for a finite period of time in the presence of mild or moderate depression. However, if significant improvement does not occur, a trial of antidepressant medication should be considered.

The use of subjective and objective diagnostic measurement tools is an effective method of monitoring clinical improvement. If psychotherapy is chosen as the initial treatment and there is no clinical improvement noted after six weeks or only partial improvement has occurred after 12 weeks, a referral to, or consultation with, a psychiatrist is advised. If there is no referral for refractory symptoms after this designated time period, there should be documentation in the medical record detailing why a referral or consultation has not taken place.

Somatic Treatments

Antidepressant Medication

Studies indicate a similar rate of therapeutic response for all antidepressant medications. Therefore, no single antidepressant can be recommended as superior overall. Selection of a specific antidepressant medication should be based upon the side effect profile, the patient's psychiatric and medical history, family history of psychiatric treatment response, convenience in taking the medication, medications being used for other illnesses, vital signs, and laboratory or EKG studies when appropriate. Following initiation of pharmacotherapy, significant improvement may not be demonstrated for up to six weeks.

Recently, there has been some concern that the use of antidepressant medications themselves may induce suicidal behavior in youths. Following a thorough and comprehensive review of all the available published and unpublished controlled clinical trials of antidepressants in children and adolescents, the U.S. Food and Drug Administration (FDA) issued a public warning in October 2004 about an increased risk of suicidal thoughts or behavior (suicidality) in children and adolescents treated with SSRI antidepressant medications. In 2006, an advisory committee to the FDA recommended that the agency extend the warning to include young adults up to age 25.

In response, the FDA adopted a "black box" label warning indicating that antidepressants may increase the risk of suicidal thinking and behavior in some children and adolescents with MDD. For many antidepressants, the boxed warning includes the following statement: "[Drug Name] is not approved for use in pediatric patients less than 12 years of age. You should always ask your doctor if a proposed antidepressant for your child is approved for use in children."

Implementation of Treatment

Management of Major Depressive Disorder should be integrated with other elements of the patient's overall treatment plan. If more than one clinician is involved in providing care for the patient with Major Depressive Disorder, it is essential that all treating clinicians have regular contact with one another to share relevant information in order to guide treatment decisions.

Patients who take antidepressants should be carefully monitored to evaluate for response to treatment. The use of subjective and objective diagnostic measurement tools is an effective method of monitoring clinical improvement. Vigilance for emerging side effects, changes in overall clinical condition, response to therapy, and risk of harm must be ongoing and continuous. Factors that determine the frequency of ongoing monitoring include the severity of the patient's condition, the patient's level of cooperation, availability of social supports, and the presence of comorbid risk factors. Visits to the Behavioral Health Provider should also be used to monitor suicidality and help promote treatment adherence.

Side Effects

Compliance with the prescribed antidepressant medication regimen is essential to the successful treatment of Major Depressive Disorder. However, it has been noted that 10 to 15 percent of people will discontinue their antidepressant medications within the first three weeks of treatment. Monitoring for drug-induced side effects by the physician is important to enhance compliance and allow the physician to select an antidepressant that will maximize adherence to the treatment plan.

Phases of Treatment

Acute Phase

It is not uncommon for patients to experience a significant but incomplete response to treatment during the Acute Phase. The conclusion of the Acute Phase of treatment is not achieved until maximum response and improved function have occurred. This phase commonly lasts six to 12 weeks, but the time frame may vary. In the absence of an emergent or urgent situation, the initial medication dose should be relatively low and then incrementally raised as tolerated to achieve a therapeutic effect. Blood levels, when available, may be beneficial to help with proper titration of the medication dose. The simultaneous co-administration of psychotherapy has demonstrated improved treatment outcomes of Major Depressive Disorder by helping to maintain therapeutic gains and by delaying or preventing relapse.

Patients who are diagnosed with a new episode of Major Depressive Disorder and treated with antidepressant medication should have at least three follow-up visits during the first 12 weeks of treatment. At least one of the three follow-up contacts should be with a prescribing physician.

Continuation Phase

Continuation treatment is based upon the belief that following a successful symptomatic recovery from Major Depressive Disorder, continuation of antidepressant medication must occur to prevent relapse. Patients who respond to antidepressant medication should continue to receive full therapeutic doses of medication for at least six months after symptomatic recovery. In general, the same dose of medication used in the Acute Phase should be continued during the Continuation Phase. If it has

been determined that the medication should be tapered and discontinued after that period of treatment, close monitoring is required to ensure a stable remission and to evaluate for relapse.

Maintenance Phase

Maintenance treatment should be considered for patients who have experienced more than one episode of major depression. If the patient has experienced more than two episodes of major depression, the mental health professional must document discussion of maintenance therapy during or after each subsequent episode of major depression. In general, treatment demonstrated to be effective during the Acute and Continuation Phases should be used in the Maintenance Phase. Antidepressant doses should also remain the same as those established during the Acute and Continuation Phases, unless a dosage change is clinically warranted by side effects or drug interactions.

For those individuals who have had one episode of Major Depressive Disorder, between 50 and 85 percent will have at least one recurrence, often within two to three years.

Discontinuation of Active Treatment

The decision to discontinue active treatment should be based upon the same information that had been considered regarding maintenance treatment. These factors include the probability of recurrence, frequency and severity of symptoms in past depressive episodes, persistence of dysthymia, risk factors, presence of comorbid conditions and patient preferences.

Medication-Resistant Depression

Initial treatment of Major Depressive Disorder with antidepressant medication fails to achieve a satisfactory response in 20 to 40 percent of patients. In some cases, a failed response may be related to an incorrect diagnosis, inadequate treatment, failure to diagnose and treat comorbid general medical or psychiatric illnesses or other complicating psychosocial problems. If the patient does not exhibit improvement in symptoms within four to six weeks, modification of medication dosage and/or intervention should occur. If an alteration in treatment does not occur for unresponsive symptoms after six weeks, the rationale that justifies this lack of a change in the treatment plan must be documented. A minimum of two medications in different categories should be tried before a patient is considered treatment-resistant. The absence of the expected patient response to a particular medication should precipitate a re-evaluation of the diagnosis. Simultaneous use of multiple antidepressant medications may be considered as well as the addition of an adjunct to the existing medication profile. Adjunctive medications include lithium, thyroid hormone, and psychostimulants, among others. Electroconvulsive Therapy (ECT) should also be considered in virtually all cases of medication-resistant depression because approximately 50 percent of medication-resistant patients will respond to ECT. Anticonvulsant medications have also demonstrated some benefit in the treatment of medication-resistant depression.

Electroconvulsive Therapy (ECT)

ECT represents a usually safe and effective treatment for severe Major Depressive Disorder. ECT has an excellent safety profile and generally has a rapid response time. It is generally not recommended as a primary treatment for uncomplicated Major Depressive Disorder in part because of its reputation and also because of its invasive nature.

ECT may be considered as initial treatment in the following clinical situations:

- Major Depressive Disorder with psychotic features
- Severe suicidality
- Catatonic stupor
- Food refusal leading to nutritional compromise
- Situations where a rapid antidepressant response is indicated
- History of prior treatment benefit from ECT

ECT may be considered as secondary treatment in patients with moderate to severe depression that is not responsive to pharmacological interventions.

The evaluation preceding ECT should include:

- Psychiatric history and physical examination
- General medical assessment, including electrocardiogram, complete blood count, liver function tests, electrolytes and CT scan of the head when clinically indicated (medical assessment must be performed within one month of the initiation of initial ECT)
- Anesthesia evaluation
- Patient informed consent obtained by the physician who will perform the ECT
- Documentation that the clinical indications, potential benefits and potential risks of ECT were discussed with the patient

It is important that the clinician discuss the possibility of ECT with a patient prior to pursuing a prolonged series of medication trials.

The current standard for ECT is a maximum of three treatments per week.

Indications for multiple monitored ECT include:

- Patients who exhibit poor response to a standard course of ECT
- Patients who are at significantly increased risk for complications from anesthesia

Following six ECT treatments (if not before), medical record documentation should indicate the extent of clinical improvement. If no improvement is evident, then rationale for the continuation of ECT must be written in the medical record. If there is not significant improvement after 12 treatments, ECT should be discontinued. The use of subjective and objective diagnostic measurement tools is an effective method of monitoring clinical improvement.

Patients who are stabilized with ECT and who require maintenance treatment may be given a trial of antidepressant medication. Maintenance ECT may also be considered. Maintenance ECT treatments are usually given monthly, but may be required at more frequent intervals as clinically indicated.

Primary side effects of ECT are cognitive, which include transient postictal confusion with potential periods of anterograde and retrograde memory disturbance. Other side effects related to general anesthesia may be encountered. Patients rarely report persistent cognitive disruption.

Investigational Treatments

Based on current research, the Company has determined that the following treatments for Major Depressive Disorder have not demonstrated equivalence or superiority to currently accepted standard means of treatment and are considered investigational and not medically necessary.

Vagus Nerve Stimulation (VNS)

Vagus nerve stimulation (VNS) is an adjunctive, invasive treatment that is sometimes proposed for individuals with a chronic major depressive disorder to decrease the severity and duration of depressive signs and symptoms. This treatment is considered for individuals resistant to all other forms of therapy. The device delivers an intermittent electrical current to the vagus nerve, which then stimulates areas of the brain believed to be involved in mood regulation. Electrical impulses arise from a surgically implanted generator.

Repetitive Transcranial Magnetic Stimulation (rTMS)

Repetitive Transcranial Magnetic Stimulation (rTMS) is a noninvasive technique that is being investigated as a treatment for major depression. Brief pulses of magnetic energy are applied to the scalp via a large electromagnetic coil to generate low levels of electrical current in the underlying brain tissue. The goal is stimulation of the areas of the brain involved in mood regulation in order to lessen the duration and severity of depressive episodes.

ENROLLMENT IN THE DEPRESSION DISEASE MANAGEMENT PROGRAM

The Depression Program augments your treatment by providing members with educational tools that stress treatment compliance, self-management, and self-monitoring. Health coaches augment the prescribed treatment plan while you continue to direct the care. Referred members who agree to participate will be screened using the PHQ-9. To refer a member for screening and possible enrollment in the program or if you have questions, call 800/861-4826.

MANAGEMENT OF THE SUICIDAL PATIENT

Risk Factors

Patients with Major Depressive Disorder are at an increased risk for suicide. There should be documentation that an initial assessment for suicidal ideation was performed and ongoing re-evaluations should occur throughout the entire treatment course.

General Management

General principles pertaining to management of the patient with suicidal ideation include:

- Provide the patient with an explanation of the etiology of Major Depressive Disorder, the prognosis and the proposed treatment plan. Inform the patient that feelings of hopelessness and suicidal thoughts are frequently related to Major Depressive Disorder and should abate when the depression resolves.
- The patient should be encouraged to make an agreement to contact the provider if the patient should feel intensely suicidal.
- Advise the patient to discontinue all alcohol and unprescribed or illegal drugs.
- Involve family members when appropriate in treating the suicidal patient.
- Provide frequent supportive interactions with the patient when suicidal ideation indicates a high risk. Treatment should continue until suicidal ideation abates.
- Reassess the patient's condition for suicidal ideation and risk factors at each treatment visit.
- Consider alternate levels of care for people who represent an active suicide risk.
- Recognize that the risk of suicide is increased during the early stages of treatment.

COMMUNICATION AND CONTINUITY

Patient Education

There must be documentation in the treatment record that the patient received verbal and/or written education regarding Major Depressive Disorder. When permitted by the patient, there should also be education of the patient's family/significant others regarding the care process.

Communication with the Primary Care Physician

In order to provide continuity of care and synergistic medical management, a written clinical summary should be sent to the Primary Care Physician or other referring provider within 30 days following the initial patient evaluation. If the treating Behavioral Health Professional does not communicate with the referring provider, an explanation for the absence of communication should be documented in the medical record. All communications of individually identifiable health information must be in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

There should be evidence of the following in each treatment record:

- **Authorization:** The Behavioral Health Provider is advised to obtain written authorization from the patient prior to communicating any information to the Primary Care Physician or Referring Provider. The Behavioral Health Provider should explain the importance of professional to professional information sharing and should seek permission from the patient to allow a medical communication to be sent to the Primary Care Physician or Referring Provider. The patient's response to this request must be recorded in the medical record.
- **Written Communication:** The Behavioral Health Provider must develop a written clinical summary that addresses the patient's condition and proposed treatment plan.
- **Timeliness:** The written summary must be completed and sent within 30 days following the initial evaluation by the Behavioral Health Provider. Additional correspondence should be sent whenever significant changes occur.
- **Interventions and Goals:** Therapeutic interventions and treatment goals for the current Major Depressive Disorder episode.
- **Patient Management:** Medical record documentation delineating the proposed therapy and/or ongoing therapeutic recommendations (e.g., medication dosages and schedule, psychotherapy, ECT frequency, behavioral modification).
- **Continuity:** Recommendations pertaining to follow-up care, including specific details regarding the process for patient follow-up as indicated.

Communication between Behavioral Health Providers

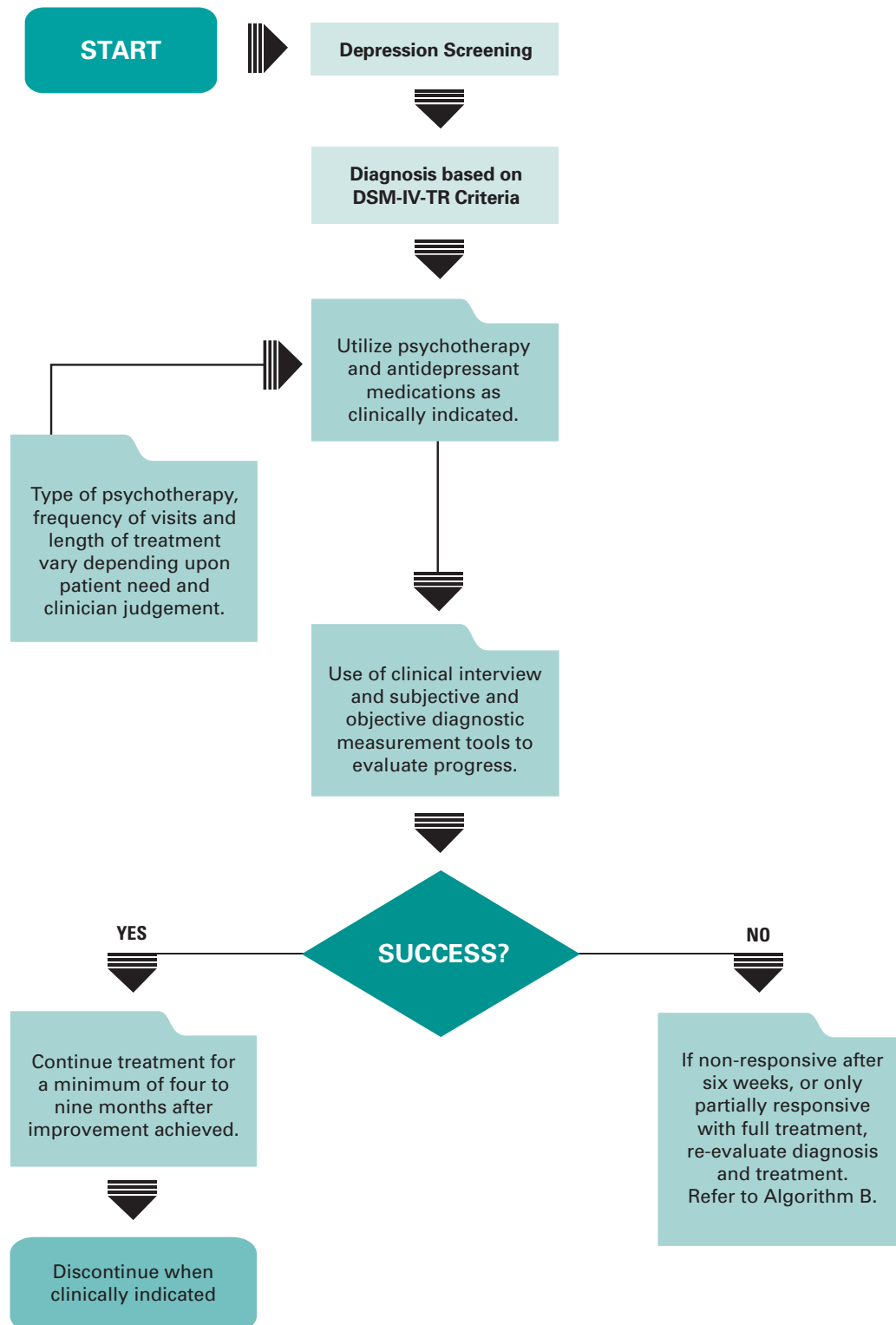
Verbal or written communication between the various attending Behavioral Health Providers (e.g., inpatient psychiatrist and outpatient psychologist) is crucial to ensuring continuity and coordination of care. Signed patient authorization is recommended to permit this communication. Medical record documentation of this communication, or the patient's refusal to authorize communication, is strongly recommended.

Documentation

Legibility is an essential component of comprehensive documentation. Medical record documentation of the initial patient evaluation should include use of the Axis format. The Axis format is the current industry standard for documentation and ensures that each patient is thoroughly evaluated and that all factors contributing to the diagnosis of Major Depressive Disorder (i.e., medical conditions) are addressed. All five Axes must be documented for every patient.

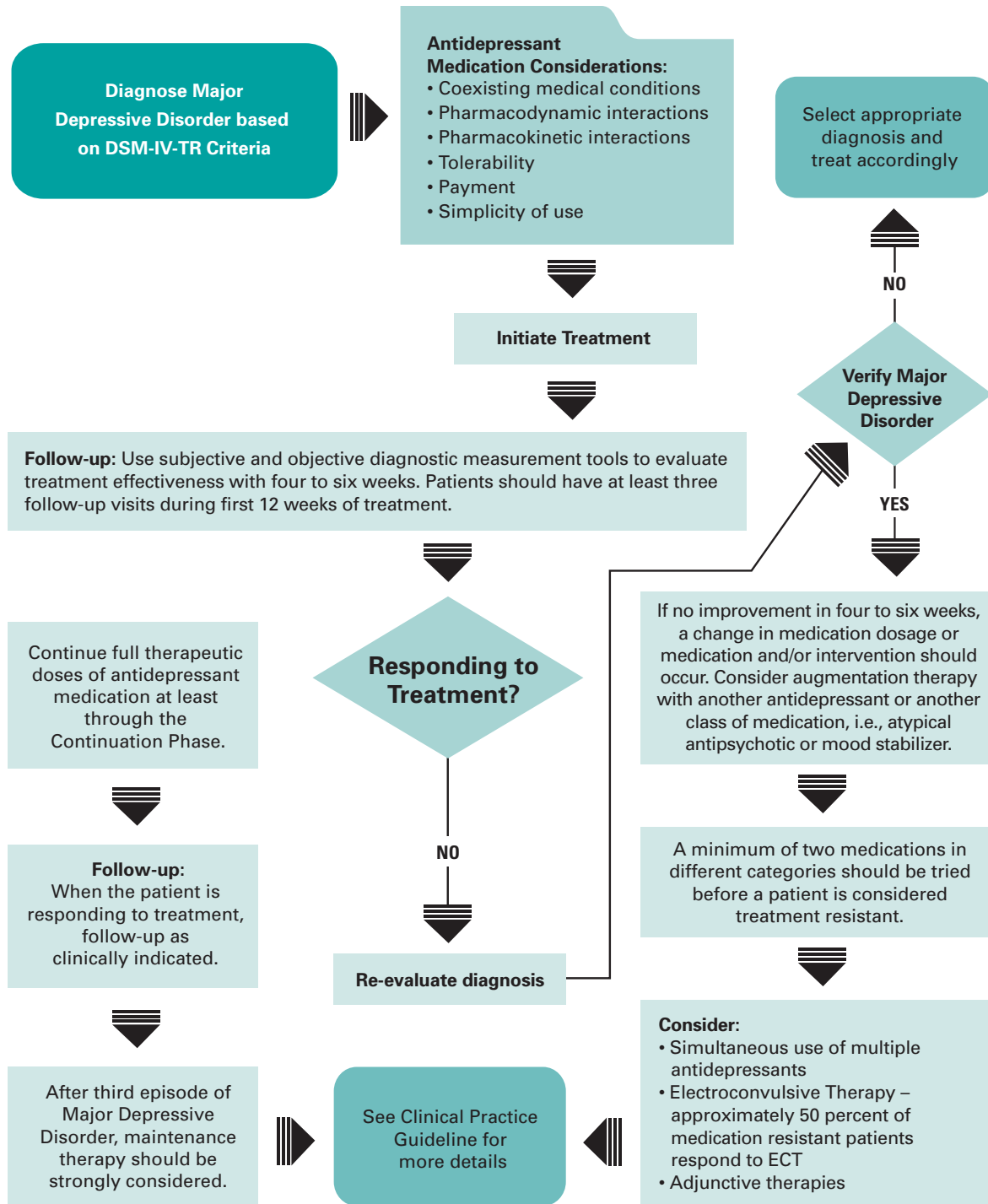
ALGORITHM A

OVERVIEW OF THE TREATMENT OF MAJOR DEPRESSIVE DISORDER



ALGORITHM B

ANTIDEPRESSANT MEDICATION MANAGEMENT



ALGORITHM C

ELECTROCONVULSIVE THERAPY (ECT)



REFERENCES

1. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000.
2. American Psychiatric Association: Practice Guideline for Major Depressive Disorder in Adults. Washington, DC, American Psychiatric Association, 1993 (revised 2000).

DISEASE AND MATERNITY MANAGEMENT PROGRAM

We are committed to serving the healthcare needs of our members. To assist individuals diagnosed with chronic diseases or who are pregnant, we offer the *SuperWell Disease and Maternity Management Program*. The program helps members who have chronic conditions or who are pregnant better manage their care by providing specially trained health coaches who offer structured education and support to increase a member's knowledge of their disease or pregnancy. In addition, health coaches work with the member to teach them how to avoid potential complications and the importance of complying with their prescribed treatment plan. Members benefit from routine monitoring of their condition by their health coach with program emphasis on improving a member's overall well-being.

We currently offer the *SuperWell Disease and Maternity Management Program* for eligible members who are pregnant or diagnosed with one or more of the following conditions:

- Congestive heart failure
- Chronic obstructive pulmonary disease
- Diabetes
- Coronary artery disease
- Asthma
- Chronic pain conditions
- Depression

For more information or to enroll a member, please call 800/861-4826, or visit one of our Web sites, MedMutual.com, ConsumersLife.com or CarolinaCarePlan.com.

CLINICAL PRACTICE GUIDELINES 2010

MAJOR DEPRESSIVE DISORDER FOR
BEHAVIORAL HEALTH PROVIDERS

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