

ReviewTex
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Notice of Independent Review Decision

Date notice sent to all parties:

May 28, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medication Abilify Tab 5mg 30.000/30

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified Psychiatrist

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Clinical notes 08/21/02-04/08/13
RME 04/19/11
Previous utilization reviews 03/11/13 and 04/11/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who reported an injury to her right hip. Clinical note dated 08/21/12 detailed the patient complaining of depressive symptoms. The patient stated that she was having disorganized and erratic sleep patterns along with crying spells and feelings of hopelessness. The patient felt discouraged with physical therapy secondary to a previous failure with both surgeries and therapy. The patient utilized Effexor, Adderall, and alprazolam. The patient presented as being tearful at

times with feelings of desperation and anxiety. Clinical note dated 08/04/08 detailed the patient using an extensive list of pharmacological interventions including Cymbalta, Topamax, Wellbutrin, Xanax, Zyrtec, Singulair, Carisoprodol, Celebrex, vista, fomitadine, HCTZ, Lorcet, Maxalt, and verapamil. Clinical note dated 09/18/09 detailed the patient continuing with extensive list of medications. The patient utilized a walker for ambulatory assistance. The patient stated that she sometimes went days without getting out of the house. The patient continued with feelings of depression. Clinical note dated 06/29/10 detailed the patient not utilizing Abilify despite the medication being prescribed to her. Clinical note dated 04/11/11 detailed the patient continuing with feelings of sadness and lacking motivation. RME dated 04/28/11 detailed the patient previously undergoing ORIF at the right hip in 1999. The patient also underwent ORIF at the left wrist in 2003, total hip replacement in 2008. The patient underwent psychological evaluation which indicated the patient scored a 30 on her BDI and 39 on her BAI. Furthermore the patient scored a 53 on her FABQ-W and a 24 on her FABQ-PA. Clinical note dated 05/16/12 detailed the patient demonstrated an increase in confusion. The patient presented as being tearful. Clinical note dated 11/01/12 detailed the patient undergoing left shoulder surgery. The patient also underwent inpatient stay at residential rehabilitation facility. Her husband was hospitalized secondary to ongoing weakness and multiple infections. The patient utilized Abilify 5mg with some benefit. However the patient continued with depression. Clinical note dated 04/08/13 detailed the patient continuing with the use of Abilify. Previous utilization review dated 03/11/13 resulted in a denial for request for Abilify as insufficient evidence was presented for any significant symptoms including atypical psychosis. Utilization review dated 04/11/13 resulted in denial for Abilify as no objective findings were submitted of the response to Abilify.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Clinical documentation submitted for review notes the patient complaining of ongoing feeling of hopelessness, depression, and anxiety. Official Disability Guidelines recommend the use of Abilify as an antipsychotic medication specifically in conjunction with first-line medication therapy. Clinical documentation detailed the patient utilizing extensive list of antipsychotic medications. However, no information was submitted regarding an objective functional improvement with the use of Abilify in conjunction other antipsychotic medications. Given this, the request is not indicated as medically necessary. As such it is the opinion of this reviewer that the use of Abilify 5mg tablets is not medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

**MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE
IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Anxiety medications in chronic pain

Recommend diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Benzodiazepines are not recommended for long-term use unless the patient is being seen by a psychiatrist. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Descriptions of each are included below. Anxiety affects millions of Americans and leads to a decreased quality of life and productivity. In any given year approximately 40 million American adults ages 18 and older have an anxiety disorder (approximately 18.1 percent). Approximately 62% of anxiety disorders are associated with other mental health disorders, in particular depression. Substance abuse is also a frequent co-morbid condition. Anxiety and chronic pain: Anxiety is commonly found in patients with chronic pain, with the most common disorders being specific phobia (12.5% to 15.7%), SAD (8.3% to 11.8%) and PTSD (7.3% to 10.7%). These rates are higher than those found in the general US population. There is some evidence to suggest that anxiety disorders precede the onset of pain. Research is still needed to determine the temporal sequence. (Roy-Byrne, 2008) (Baldwin, 2005) (Bandelow, 2002) (Hoffman, 2008) Overview of pharmacotherapy: The anxiety disorders with the greatest evidence for the efficacy of pharmacotherapy are GAD, PD, and SAD, and OCD. There is more limited evidence for pharmacotherapy for PTSD. Many antidepressants, in particular the Selective Serotonin Reuptake Inhibitors (SSRIs) are considered first-line agents in the treatment of most forms of anxiety. They have a more favorable side-effect profile than monamine oxidase inhibitors (MAOIs) or tricyclic antidepressants (TCAs). They also have the advantage of treating comorbid depression. Selective Norepinephrine Reuptake Inhibitors (SNRIs), in particular Effexor® (venlafaxine) have also been proven to be effective in the treatment of many anxiety disorders. Benzodiazepines are often used to treat anxiety disorders; however, many guidelines discourage the long-term use of benzodiazepines due to sedation effects and potential for abuse and psychological dependence. Long-term use is often associated with withdrawal symptoms. Some other drug classes used to treat anxiety are antihistamines (e.g. hydroxyzine), 5HT1 agonist (e.g. buspirone), and some anti-epilepsy drugs. (Specific Treatment: FDA-approved indications are listed next to each specific drug. A note is made if a medication is used off-label.) (Hoffman, 2008)

(1) GENERALIZED ANXIETY DISORDER (GAD): GAD is characterized by anxiety/tension, excessive worry, restlessness, fatigability, poor concentration, irritability, muscle tension and poor sleep. Treatment for GAD is patient specific and the following serves only as a guide in providing pharmacotherapy. Some patients may require adjunctive psychotherapy, such as cognitive behavioral therapy (CBT) or may prefer psychotherapy, instead of pharmacotherapy. (Zwanzger, 2008) SSRIs

or SNRIs are typically first line agents for GAD. TCAs such as imipramine have been shown to be somewhat effective, but are not recommended as first-line agents due to side effects in particular. Outcomes are measured with tests such as the Hamilton Rating Scale for Anxiety (HAM-A), the Clinical Global Impression Improvement (CGI-I) scale and Clinical Global Impression Severity (CGI-S) scale. (Hoffman, 2008) (Kapczinski-Cochrane, 2003) (Schmitt, 2005)

(a) SSRIs: Escitalopram (Lexapro®, no generic available): also approved for major depressive disorder. Dosing information: 10-20 mg once daily. Paroxetine (Paxil®, generic available): Also recommended for PD, SAD, OCD, and PTSD as well as major depressive disorder. Dosing information: 20-50 mg daily. (Package insert, GlaxoSmithKline) Setraline (Zoloft®, generic available): Studies have shown effectiveness but not FDA-approved for this indication. Dosing information: 50-150 mg daily.

(b) SNRIs: Duloxetine (Cymbalta®, no generic available): also approved for major depressive disorder. Dosing information: 30-120 mg daily. Venlafaxine extended release (Effexor XR®, generic available): also recommended for PD and SAD as well as major depressive disorder. Dosing information: 75-225 mg daily. It may be recommended for some patients to start at 37.5 mg for the first 4 to 7 days. (Package insert)

(c) 5-HT_{1A} Agonist: Buspirone (Buspar®, generic available): also approved for short-term relief of anxiety symptoms. Efficacy is decreased in patients with recent prior benzodiazepine use. (Chessick, 2006) Dosing information: 5-15 mg three times daily. (Package insert)

(d) Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect. Diazepam (Valium®, generic available): Dosing information: 5-15 mg daily. Clonazepam (Klonopin®, generic available): Dosing information: 1-2 mg up to TID.

(e) TCAs (Tricyclic antidepressants): This class of medications is an effective treatment for GAD but few studies have investigated their use for DSM-IV defined GAD. Their use is limited by poorer tolerability.

(f) Other medications that may be useful: Hydroxyzine (Atarax®, generic available): Dosing information: 50 mg/day. Pregabalin (Lyrica®, generic available): Non-FDA approved indication. Dosing information: 50-200mg three times daily (with a general range of 200-450 mg a day) Atypical antipsychotics: Olanzapine (Zyprexa®) and Risperidone (generic available): used as an adjunct agent.

(2) PANIC DISORDER (PD) with and without agoraphobia: Panic disorder (PD) is described by the DSM-IV-TR to include periods of intense fear that peak within 10 minutes. Symptoms include palpitations, sweating, shortness of breath and lightheadedness. Patients often have persistent worry about having further attacks. PD can occur with or without agoraphobia (anxiety about and avoidance of being in situations where escape may be difficult). Outcomes are measured in terms of frequency and change in the total number of attacks. Testing includes the Panic Disorder Severity Scale (PDSS). (Hoffman, 2008) (Mitte, 2005) (Otto, 2001) (Furukawa, 2007)

(a) Maintenance treatment: SSRIs are first-line medications based on safety and tolerability. If the patient does not respond, another SSRI should be attempted. If this fails, another class of medications should be attempted (SNRI, TCA or benzodiazepine). Fluoxetine (Prozac®, generic available): Also approved for major depressive disorder, OCD and premenstrual dysphoric disorder. Dosing information: 20-60 mg daily. Paroxetine (Paxil®, generic available): Also recommended for GAD, SAD, OCD, and PTSD as well as major depressive disorder. Dosing information: dosing is typically 10-60 mg daily. Paroxetine CR (Paxil® CR): Also approved for SAD, major depressive disorder, and premenstrual dysphoric disorder. Sertraline (Zoloft®, generic available): Also approved for PTSD, SAD, OCD, major depressive disorder and premenstrual dysphoric disorder. Dosing information: 50-200 mg once daily. Citalopram (Celexa®, generic available): Non-FDA approved indication. Dosing information: 20-60 mg once daily. Fluvoxamine (Luvox®, generic available): Non-FDA approved indication. Dosing information: Initially 50mg at bedtime, doses should be titrated upward to daily doses of 100-300 mg daily. Daily doses greater than 100mg should be divided, with the larger dose given at bedtime. Escitalopram (Lexapro®): Non-FDA approved indication. Dosing information: 10-20 mg once daily. SNRI: Venlafaxine (Effexor XR®, generic available): also approved for GAD, SAD and major depressive disorder. Dosing information: 37.5-225 mg daily.

(b) Secondary treatment options, when other medications have failed or been intolerable to patients: Tricyclic Antidepressants (TCAs): Clomipramine (Anafranil®, generic available): Dosing information: 75-250 mg daily. (Bandelow, 2002) Imipramine (Tofranil®, generic available): Dosing information: 75-250 mg daily. (Bandelow, 2002) MAOI: Phenelzine (Nardil®, no generic available): Dosing information: 45-90 mg daily in divided doses, three times daily. Other antidepressants: Mirtazapine (Remeron®, generic available): Dosing information: 45 mg daily.

(c) Acute treatment: Benzodiazepines may be recommended with initial treatment as an adjunct agent to SSRIs as the latter class of drugs is titrated. Benzodiazepines (short acting): Alprazolam (Xanax®, generic available): Dosing information: 0.25-1 mg TID or QID. Clonazepam (Klonopin®, generic available): Dosing information: 1-4 mg daily in two divided doses. The dose should be tapered downward during discontinuation by 0.125mg twice daily every 3 days. Doses of 1 mg are just as effective as higher doses, with less adverse effects. However, some patients may benefit from higher doses. (Roche Laboratories, 2001)

(3) POST-TRAUMATIC STRESS DISORDER (PTSD)

Defined by the DSM-IV by 3 symptom clusters: re-experiencing the event; emotional numbing/avoidance of stimuli associated with trauma; and hyperarousal. These symptoms persist for more than one month. The “gold-standard” outcome test is the Clinician-Administered PTSD Scale (CAPS). There is little long-term literature in regards to pharmacotherapy and PTSD. (Hoffman, 2008) (Stein, 2006)

(a) SSRIs: considered first-line agents in the treatment of PTSD. Paroxetine (Paxil®, generic available): Also recommended for GAD, SAD, OCD, and PD as well as major depressive disorder. Dosing information: 20-50mg daily (Bandelow, 2002) (PPI GlaxoSmithKline, 2004) Sertraline (Zoloft®, generic available): Also approved for PD, SAD, OCD, major depressive disorder and premenstrual dysphoric disorder. Dosing information: 50-200mg daily. Fluoxetine (Prozac®, generic available): Dosing information: 20-40mg daily. (Bandelow, 2002) (Clinical Pharmacology, 2008)

(b) TCAs: Amitriptyline (Elavil®, generic available): Dosing information: 75-200mg daily.

(c) Other agents shown to be potentially effective in treating PTSD: Antipsychotics: Risperidone: This medication may be beneficial as an adjunct treatment. Alpha-1 Adrenergic Agents: Prazosin, an FDA-approved antihypertensive may be helpful as a treatment for nightmares secondary to PTSD.

(4) SOCIAL ANXIETY DISORDER (SAD):

The DSM-IV-TR describes generalized SAD as a persistent fear of social situations, with exposure leading to anxiety and avoidance. Outcomes: Most studies have used the Liebowitz Social Anxiety Scale (LSAS). (Hoffman, 2008) (Schneier, 2006) (Hedges, 2007) (Ipser, 2008)

(a) SSRIs: generally recommended as first-line agents for treating SAD, due to effectiveness and favorable side effect profile. The initial dose is generally half of the usual dose. Titration can occur over 1 week to 4 weeks. A trial of a SSRI is recommended for at least 12 weeks as some patients take over 8 weeks for a response. Maintenance therapy is recommended for those patients who take over 8 weeks for response to prevent relapse. Medications are indicated for at least 6 to 12 months with follow-up for relapse. (Schneier, 2006) Paroxetine (Paxil®, generic available): Also recommended for GAD, PD, OCD, and PTSD as well as major depressive disorder. Dosing information: 20-60mg daily. (Bandelow 2002)

Paroxetine controlled release (Paxil CR®, generic available): Also approved for PD, major depressive disorder, and premenstrual dysphoric disorder. Dosing information: Initially 12.5 mg daily, may increase up to 37.5mg daily. (PPI GlaxoSmithKline) Sertraline (Zoloft®, generic available): Also approved for OCD, major depressive disorder and premenstrual dysphoric disorder. Dosing information: 50-150 mg daily (max 200 mg daily). Escitalopram (Lexapro®, no generic available): Non-FDA approved indication. Dosing information: 10-20 mg once daily. Fluvoxamine (Luvox®, generic available): Non-FDA approved indication. Dosing information: Initially 50 mg at bedtime, doses should be titrated upward to daily doses of 100-300 mg daily. Daily doses greater than 100 mg should be divided, with the larger dose given at bedtime.

(b) SNRI: Considered a first-line medication for generalized SAD. Venlafaxine (Effexor XR®, generic available): also approved for GAD, PD and major depressive disorder. Dosing information: 37.5-225mg daily. Generally started at half of the usual dose and increased over the first week of treatment. Doses can then be increased over a 4-week period.

(c) Other agents used as secondary or alternative treatment to SSRIs: (Schneier, 2006) Benzodiazepines: Clonazepam (Klonopin®, generic available): Dosing information: See Generalized Anxiety Disorder. Anticonvulsants: Gabapentin (Neurontin®, generic available): non-FDA approved indication. Dosing information: 900-3600 mg per day in divided doses. Pregabalin (Lyrica®): Non-FDA approved indication. Dosing information: 300-600 mg.

(5) OBSESSIVE COMPULSIVE DISORDER (OCD): Characterized by recurrent obsessional ruminations, images or impulses, and/or recurrent physical or mental rituals. These ruminations interfere with social and occupational function. OCD is thought to respond selectively to drugs that inhibit the synaptic reuptake of serotonin. An adequate trial should consist of 10-12 weeks with at least 4-6 weeks at

the maximum tolerated dose. Cognitive-behavioral therapy may need to be considered. (Soomro, 2008) (Baldwin, 2005)

(a) SSRIs: Fluoxetine (Prozac®, generic available): Dosing information: 20-80 mg daily, doses greater than 40 mg daily should be divided. Fluvoxamine (Luvox®, generic available): Dosing information: doses should be titrated to a range of 100-300 mg, with doses greater than 100 mg daily in divided doses. Paroxetine (Paxil®, generic available): Dosing information: Initially 20mg (optimal dose is 40mg/day); max dose is 60mg daily. Sertraline (Zoloft®, generic available): Dosing information: 50-200 mg daily.

(b) TCAs: Clomipramine (Tofranil®, generic available): Dosing information: Initially 25 mg daily, dose should be titrated upward to doses from 75-250 mg daily. Dose may be given at bedtime to reduce the incidence of daytime sedation. Note: During the initial titration of clomipramine, the dose may be given in divided daily doses in order to minimize GI effects. (PPI Mallinkrodt Inc.)

(c) Benzodiazepines for severe cases, treatment resistant cases or adjunctive therapy: Clonazepam (Klonopin®, generic available).

(d) Other agents used for treatment resistant patients (Adjunct therapy): If there is no response to one of the above drugs, the suggestion is to try another first-line alternative. Then adjunct therapy is suggested. This includes the combination of a SSRI and clomipramine, or the use of one of the above with a benzodiazepine, buspirone, antipsychotic, or mood stabilizer. If there is no response a MAOI inhibitor may be required. (Dell'Osso, 2007)