Clinical Policy Title: Depression treatment during pregnancy

Clinical Policy Number: CCP.1339

Effective Date: October 1, 2017
Initial Review Date: September 21, 2017
Most Recent Review Date: October 2, 2018
Next Review Date: October 2019

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of antidepressants and psychotherapy in pregnancy to be clinically proven and, therefore, medically necessary for the treatment of depression during pregnancy (U.S. Preventive Services Task Force, 2016; Sockol, 2015; American College of Obstetricians and Gynecologists, 2008).

- For mild to moderate depression, psychotherapy may be effective alone.
- For severe depression, pharmacotherapy may be more effective than psychotherapy alone.

The benefits and risks of potential treatments being considered should be carefully weighed and discussed in a collaborative care model.

Limitations:

Select Health of South Carolina considers the use of the following treatment approaches to depression in pregnancy, among others, to be investigational/experimental and, therefore, not medically necessary.

- Acupuncture.
- Botulinum toxin.
• Bright light therapy.
• Exercise.
• Mindfulness-based interventions.
• Nutritional supplements.
• Transcranial magnetic stimulation.
• Yoga.

Alternative covered services:

None.

Background

Depression is a disabling disease that is associated with serious physical, behavioral, and social repercussions. These include increased rates of mortality from suicide and from other illnesses; other mental health conditions including smoking, substance abuse, and eating disorders; and absenteeism resulting in reduced income.

A major depressive episode is defined as a period persisting at least two weeks during which a person has a depressed mood or loss of interest or pleasure in daily activities, along with some additional difficulties such as problems with sleeping, eating, concentrating, energy, and/or feelings of self-worth, without mania, and not due to another physiological cause, causing “clinically significant distress or impairment” (American Psychiatric Association, 2013). Bipolar disorder is a distinct disease from depression. Persons who experience one episode of depression have a 50 percent likelihood of another episode, increasing the potential for future depressive episodes (American Psychiatric Association, 2000).

Based on a national survey, it is estimated that 16.1 million adults in the United States, or nearly seven percent of the adult population, experienced a major depressive episode in 2015 (Center for Behavioral Health Statistics and Quality, 2016). About a third (32.8 percent) did not receive treatment (defined as medication or some type of counseling). Among adolescents, 12.5 percent (an estimated 1.2 million youth ages 12 to 17) said they had a major depressive episode in the previous year, and 60.7 percent said they had not received treatment. Beginning at age 12, depressive symptoms and diagnoses are two to three times higher in females than in males (Salk, 2012). In sum, those women at ages associated with the highest fertility have the highest rates for major depressive episodes, yet the lowest rates of receiving treatment.

Risk factors for antenatal depression include high anxiety and perceived stress; adverse life events; unintended or unwanted pregnancy; low social support, income, or education; poor relationship quality; history of abuse or domestic violence; history of mental illness; adolescent age; and pregnancy complications (Biaggi, 2015; Lancaster, 2010). Depression rates among women with an unintended
pregnancy are 21 percent, double the rates among women with a planned pregnancy (Abajobir, 2016).

Depression in pregnancy is associated with increased risk to both the woman and the fetus. Maternal depression is associated with suboptimal nutrition; poor-quality sleep; preterm birth; low birth weight; neonatal intensive care admission; and postpartum depression (Jarde, 2016; Baskin, 2015; Araujo, 2010). Prenatal maternal stress including depression may be associated with atopic conditions (asthma, wheeze, atopic dermatitis, allergic rhinitis, and IgE) in the offspring (Andersson, 2016).

The American College of Obstetricians and Gynecologists (2010) recommends that women be screened at least once during the perinatal period for depression and anxiety using a validated, standardized instrument and that women with current depression or anxiety, or risk factors or history of perinatal mood disorders, be particularly closely monitored, evaluated, and assessed.

The following recommendation was published by the Institute for Clinical Systems Improvement (Triangle, 2016):

“Clinicians should screen and monitor depression in pregnant and postpartum women...Although direct evidence of the isolated health benefit of depression screening in primary care is weak, the totality of the evidence supports the benefits of screening in pregnant and postpartum women, particularly in the presence of additional treatment supports such as treatment protocols, care management, and availability of specially trained depression care providers.”

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 3, 2018. Search terms were: “depression” (MeSH) and “pregnancy” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple
cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The following treatment recommendation was published by the U.S. Preventive Services Task Force (2016).

“Effective treatment of depression in adults generally includes antidepressants or specific psychotherapy approaches (e.g., cognitive behavioral therapy [CBT] or brief psychosocial counseling), alone or in combination. Given the potential harms to the fetus and newborn child from certain pharmacologic agents, clinicians are encouraged to consider CBT or other evidence-based counseling interventions when managing depression in pregnant or breastfeeding women.”

The following specific recommendations and conclusions regarding pharmacologic treatment for depression in pregnancy are from the American College of Obstetricians and Gynecologists (2008, reaffirmed 2012):

“The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Lithium exposure in pregnancy may be associated with a small increase in congenital cardiac malformations, with a risk ratio of 1.2 to 7.7.
- Valproate exposure in pregnancy is associated with an increased risk of fetal anomalies, including neural tube defects, fetal valproate syndrome, and long term adverse neurocognitive effects. It should be avoided in pregnancy, if possible, especially during the first trimester.
- Carbamazepine exposure in pregnancy is associated with fetal carbamazepine syndrome. It should be avoided in pregnancy, if possible, especially during the first trimester.
- Maternal benzodiazepine use shortly before delivery is associated with floppy infant syndrome.

“The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- Paroxetine use in pregnant women and women planning pregnancy should be avoided, if possible. Fetal echocardiography should be considered for women who are exposed to paroxetine in early pregnancy.
- Prenatal benzodiazepine exposure increased the risk of oral cleft, although the absolute risk increased by 0.01%.
- Lamotrigine is a potential maintenance therapy option for pregnant women with bipolar disorder because of its protective effects against bipolar...
depression, general tolerability, and a growing reproductive safety profile relative to alternative mood stabilizers.

- Maternal psychiatric illness, if inadequately treated or untreated, may result in poor compliance with prenatal care, inadequate nutrition, exposure to additional medication or herbal remedies, increased alcohol and tobacco use, deficits in mother–infant bonding, and disruptions within the family environment.

“The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

- Whenever possible, multidisciplinary management involving the patient's obstetrician, mental health clinician, primary health care provider, and pediatrician is recommended to facilitate care.
- Use of a single medication at a higher dose is favored over the use of multiple medications for the treatment of psychiatric illness during pregnancy.
- The physiologic alterations of pregnancy may affect the absorption, distribution, metabolism, and elimination of lithium, and close monitoring of lithium levels during pregnancy and postpartum is recommended.
- For women who breastfeed, measuring serum levels in the neonate is not recommended.
- Treatment with all selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors or both during pregnancy should be individualized.
- Fetal assessment with fetal echocardiogram should be considered in pregnant women exposed to lithium in the first trimester.”

Several systematic reviews and meta-analyses provide evidence for the pharmacological treatment recommendations and guidelines above. Increased risks to fetal health associated with selective serotonin reuptake inhibitors appear to be small, and therefore may be acceptable for women with severe depression. Selective serotonin reuptake inhibitors during 91 days before or after the last menstrual period was associated with an increased rate of severe congenital heart defects and a higher rate of an aggregate outcome of anomaly or stillbirth; however, the increased prevalence of all major anomalies combined did not reach statistical significance (Jordan, 2016). There was an evident dose-response effect such that the prevalence of anomalies and severe congenital heart defects decreased when medication was paused or stopped preconception, and increased when more than one medication was prescribed. A systematic review and meta-analysis found that prenatal use of selective serotonin reuptake inhibitors was associated with a higher rate of preterm birth when compared to non-exposed controls with and without depression and to controls treated with psychotherapy (Eke, 2016). Ross (2013) found no significant association between antidepressant exposure and spontaneous abortion, but did find statistically significant associations between antidepressant exposure and the pregnancy and delivery outcomes of gestational age and preterm delivery regardless of whether the comparison group consisted of depressed but untreated mothers, or all unexposed mothers. However, group
differences were small and scores in the exposed group were typically within the normal ranges. Mezzacappa (2017) found an association with prenatal antidepressant exposure and autism spectrum disorders, while Brown (2017) did not. Brown conjectured that an observed association in some included studies may have been due to residual confounding in the measurement of maternal mental illness.

Significant decreases in depressive symptoms in treatment groups compared to controls were found in both treatment and prevention studies, leading to the conclusion that despite widely varying methodological quality of the included studies, there is strong evidence that Cognitive Behavioral Therapy interventions are effective for treating and preventing depression during the perinatal period (Sockol, 2015). An evaluation of Cognitive Behavioral Therapy showed a robust benefit; interpersonal therapy showed a medium treatment effect; however, the studies were inconsistent (van Ravesteyn, 2017). Acupuncture and body-oriented interventions showed medium reductions.

A low proportion of women meet American College of Obstetricians and Gynecologists recommendations for exercise during the third trimester, and nearly a third reported not receiving advice from a provider about physical activity during pregnancy (Santo, 2017). Any type of exercise intervention among pregnant women was associated with a significant decrease in depression scores (Daley, 2015). However, this conclusion was based on a low number of significantly heterogeneous studies with wide conference intervals. Yoga integrating pranayama and meditation or deep relaxation was effective in reducing depression scores, while yoga consisting solely of physical exercises was not (Gong, 2015). However, the small number of included studies limits certainty.

Meta-analyses on computer- or web-based therapies, mindfulness-based interventions, transcranial magnetic stimulation, acupuncture, bright light therapy, massage, and omega-3 fatty acids have not resulted in conclusive findings due to small study numbers and sample sizes, heterogeneity of study designs and interventions, and methodological issues (Ashford, 2016; Dennis, 2013; Felipe, 2016; Hall, 2016; Lever Taylor, 2016; Shi, 2017). Injections of Botulinum toxin type A ("Botox") in the facial glabellar frown muscles for depression show efficacy, but meta-analyses were based on a small number of studies and sample sizes (Magid, 2015; Hawlik, 2014). Importantly, there are inadequate data on the developmental risk associated with use of Botox in pregnant women.

Policy updates:

In 2018, we updated one guideline and added five peer-reviewed publications to the reference list. No policy changes are warranted at this time. Policy ID changed from 120106 to CCP.1339.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Brown (2017)</td>
<td>Key points:</td>
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<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| The association between antenatal exposure to selective serotonin reuptake inhibitors and autism: A systematic review and meta-analysis | - This analysis examined maternal exposure to selective serotonin reuptake inhibitors and autism in children, and assessed maternal mental illness as a confounder. Included in the meta-analysis were four case-control studies and two cohort studies.  
- In the case-control studies, the adjusted pooled odds ratio (aPOR) values were 1.4 (95% confidence interval [CI], 1.0 - 2.0) (exposure in any period) and 1.7 (95% CI, 1.1 - 2.6) (exposure during first trimester). In analyses adjusted for maternal mental illness, only first trimester exposure remained statistically significant (aPOR = 1.8; 95% CI, 1.1 - 3.1). In maternal mental illness-restricted analyses, neither exposure period was statistically significant.  
- In the cohort studies, relative risk values adjusted for maternal mental illness were 1.5 (95% CI, 0.9 - 2.7) (any period) and 1.4 (95% CI, 1.0 - 1.9) (first trimester only). In maternal mental illness-restricted analyses, exposure to selective serotonin reuptake inhibitors at any time during pregnancy was not significant. |
| Mezzacappa (2017) | Key points:  
- This analysis aimed to assess the association between autism spectrum disorders and maternal mental illness as a confounder. Included in the meta-analysis were four case-control studies and two cohort studies.  
- In the case-control studies, the adjusted pooled odds ratio (aPOR) values were 1.4 (95% confidence interval [CI], 1.0 - 2.0) (exposure in any period) and 1.7 (95% CI, 1.1 - 2.6) (exposure during first trimester). In analyses adjusted for maternal mental illness, only first trimester exposure remained statistically significant (aPOR = 1.8; 95% CI, 1.1 - 3.1). In maternal mental illness-restricted analyses, neither exposure period was statistically significant.  
- In the cohort studies, relative risk values adjusted for maternal mental illness were 1.5 (95% CI, 0.9 - 2.7) (any period) and 1.4 (95% CI, 1.0 - 1.9) (first trimester only). In maternal mental illness-restricted analyses, exposure to selective serotonin reuptake inhibitors at any time during pregnancy was not significant. |
| van Ravesteyn (2017) | Interventions to treat mental disorders during pregnancy: A systematic review and multiple treatment meta-analysis | Key points:  
- This analysis aimed to understand all available treatments for antenatal mental disorders. Twenty-nine trials on antenatal mental disorders involving 2,779 participants were found. Trials studied patients with depressive disorders (number studies = 28), and anxiety disorders (number studies = 1) during pregnancy. No controlled pharmacological trials were detected for inclusion.  
- The results showed that a form of psychotherapy, like Cognitive Behavioral Therapy (g = -0.61; 95% CI: -0.73 to -0.49, I² = 0%; number studies = 7) or interpersonal psychotherapy (g = -0.67; 95% CI: -1.27 to -0.07; I² = 79%; number studies = 4), holds robust benefit for pregnant women with major depressive disorder. |
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| O’Connor (2016)                                | - Body-oriented interventions \( (g = -0.43; 95\% \text{ CI: } -0.61 \text{ to } -0.25; I^2 = 17\%; \text{ number studies } = 7) \) and acupuncture \( (g = -0.43; 95\% \text{ CI: } -0.80 \text{ to } -0.06; I^2 = 0\%; \text{ number studies } = 2) \) showed medium-sized reduction of depressive symptoms. Bright light therapy \( (g = -0.59; 95\% \text{ CI: } -1.25 \text{ to } 0.06; I^2 = 0\%; \text{ number studies } = 2) \), and food supplements \( (g = -0.51; 95\% \text{ CI: } -1.02 \text{ to } 0.01; I^2 = 20\%; \text{ number studies } = 3) \) did not show significant treatment effects.  
- Findings show a robust moderate treatment effect for Cognitive Behavioral Therapy for major depressive disorder during pregnancy. A lesser treatment effect was found for interpersonal psychotherapy. Positive medium-size treatment effects were found for the alternatives of body-oriented interventions and acupuncture, and no evidence was found for bright light or food supplements. |
| O’Connor (2016)                                | **Key points:**  
- This study assessed the benefits and harms of depression screening and treatment, and accuracy of selected screening instruments, for pregnant and postpartum women. The outcomes examined were depression remission, prevalence, symptoms, and related measures of depression recovery or response; sensitivity and specificity of selected screening measures to detect depression; and serious adverse effects of antidepressant treatment.  
- Among pregnant and postpartum women 18 years and older, six trials \( (n = 11,869) \) showed 18\% to 59\% relative reductions with screening programs, or 2.1\% to 9.1\% absolute reductions, in the risk of depression at follow-up (three to five months) after participation in programs involving depression screening, with or without additional treatment components, compared with usual care.  
- Based on 23 studies \( (n = 5,398) \), a cutoff of 13 on the English-language Edinburgh Postnatal Depression Scale demonstrated sensitivity ranging from 0.67 (95\% CI, 0.18 - 0.96) to 1.00 (95\% CI, 0.67 to 1.00) and specificity consistently 0.87 or higher. Data were sparse for Patient Health Questionnaire instruments.  
- Pooled results for the benefit of Cognitive Behavioral Therapy for pregnant and postpartum women with screen-detected depression showed an increase in the likelihood of remission \( (\text{pooled relative risk, } 1.34 \ [95\% \text{ CI, } 1.19 \text{ to } 1.50]; \text{ number of studies } = 10, I^2 = 7.9\% \) compared with usual care, with absolute increases ranging from 6.2\% to 34.6\%.  
- Observational data showed that second-generation antidepressant use during pregnancy may be associated with small increases in the risks of potentially serious harms.  
- The authors concluded that direct and indirect evidence suggests that screening pregnant and postpartum women for depression can reduce depressive symptoms and the prevalence of depression. Evidence for improvement among pregnant women was sparser but was consistent with the evidence among postpartum women regarding the screening and treatment benefits, and screening instrument accuracy. |
| Eke (2016)                                     | **Key points:**  
- This study assessed the risk of preterm birth with exposure to prenatal selective serotonin reuptake inhibitors.  
- The primary outcome was the incidence of preterm birth <37 weeks. A subgroup analysis of studies in which controls were defined as women with depression but without selective serotonin reuptake inhibitors exposure during pregnancy was also planned.  
- Eight studies \( (1,237,669 \text{ women}) \) were included: 93,982 in the exposure group and 1,143,687 in the control group. After adjusting for confounders, the incidence of preterm birth was significantly higher in the group of women treated with selective serotonin reuptake inhibitors. |
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<th>Content, Methods, Recommendations</th>
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| Ross (2013) | Reuptake inhibitors compared with controls (i.e., both women with depression but without selective serotonin reuptake inhibitors exposure and women without depression) (adjusted OR 1.24, 95% CI 1.09 to 1.41).  
  - In the subgroup analysis of studies in which the control group was defined as women with depression without selective serotonin reuptake inhibitors exposure during pregnancy, an increased risk of preterm birth (6.8% versus 5.8%, OR 1.17, 95% CI 1.10 to 1.25) in the selective serotonin reuptake inhibitors group was found compared with depressed women treated with psychotherapy alone.  
  - Women who received selective serotonin reuptake inhibitors during pregnancy had a significantly higher risk of developing preterm birth compared with controls. This higher risk remained significant even when comparing depressed women on selective serotonin reuptake inhibitors with women not on selective serotonin reuptake inhibitors. |
| Jordan (2016) | Selective serotonin reuptake inhibitor (SSRI) antidepressants in pregnancy and congenital anomalies: Analysis of linked databases in Wales, Norway and Funen, Denmark  
  **Key points:**  
  - This international analysis included 519,117 deliveries in an examination of selective serotonin reuptake inhibitors and congenital anomalies. Fetuses terminated for congenital anomalies and data covering pregnancy and the preceding quarter, including 462,641 cases with data covering pregnancy and one year either side, were included.  
  - Selective serotonin reuptake inhibitors prescription 91 days either side of the last menstrual period was associated with increased prevalence of severe congenital heart defects (34/12,962 [0.26%] vs. 865/506,155 [0.17%] OR 1.50, 1.06 to 2.11), as well as with a composite adverse outcome of “anomaly or stillbirth” (473/12,962, 3.65% vs. 15,829/506,155, 3.13%, OR 1.13, 1.03 to 1.24). The increased prevalence of all major anomalies combined did not reach statistical significance (3.09% [400/12,962] vs. 2.67% [13,536/506,155], OR 1.09, CI 0.99 to 1.21). Adjusting for socioeconomic status left ORs largely unchanged.  
  - The prevalence of anomalies and severe congenital heart defect was reduced when selective serotonin reuptake inhibitors prescriptions were stopped or paused preconception, and increased when >1 prescription was recorded, but differences were not statistically significant. The dose-response relationship between severe congenital heart defect and selective serotonin reuptake inhibitor dose (meta-regression OR 1.49, CI 1.12 to 1.97) was consistent with selective serotonin reuptake inhibitor-exposure related risk. A sub-analysis in Wales suggested no associations between anomalies and diagnosed depression. |
  **Key points:**  
  - Forty randomized and quasi-randomized controlled trials evaluated the efficacy of Cognitive Behavioral Therapy during pregnancy and one year postpartum in both treatment and prevention studies.  
  - Cognitive Behavioral Therapy interventions resulted in significant decreases in depressive symptoms compared to control conditions in both treatment and prevention studies.  
  - Postpartum interventions showed higher efficacy than prenatal interventions. In prevention trials, individually administered treatments were more effective than group interventions and greater reductions in depressive symptoms were found in studies that included higher proportions of nonwhite, single, and multiparous participants.  
  - Methodological quality of included studies varied widely among studies eligible for inclusion. However, overall, there was strong evidence for efficacy of Cognitive Behavioral Therapy interventions for treating and preventing depression during the perinatal period. |
| Ross (2013) | **Key points:** |

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Aim: To determine whether prenatal antidepressant exposure is associated with risk for selected adverse pregnancy or delivery outcomes. The meta-analysis included 23 studies.

No significant association was found between antidepressant medication exposure and spontaneous abortion (OR 1.47; CI, 0.99 to 2.17; borderline significance). Gestational age and preterm delivery were statistically significantly associated with antidepressant exposure (mean difference in weeks = -0.45; CI - 0.64 to - 0.25; and OR 1.55; CI, 1.38 to 1.74, respectively). This held true regardless of whether the comparison group consisted of all unexposed mothers or only depressed mothers without antidepressant exposure.

Antidepressant exposure during pregnancy was significantly associated with lower birth weight (mean difference in grams = -74; CI - 117 to -31). However, when this comparison group was limited to depressed mothers without antidepressant exposure, there was no longer a significant association.

Antidepressant exposure was significantly associated with lower Apgar scores at one and five minutes, regardless of whether the comparison group was all mothers or only those who were depressed but not treated with antidepressants.

Conclusion: While statistically significant associations between antidepressant exposure and pregnancy and delivery outcomes were identified, group differences were small and scores in the exposed group were typically within the normal ranges.

References

Professional society guidelines/other:


Peer-reviewed references:


**National Coverage Determinations:**

None identified as of the writing of this policy.
Local Coverage Determinations:

None identified as of the writing of this policy.

InterQual®

InterQual Clinical Evidence Summary: Depressive disorders
InterQual 2015: BH: Adult Psychiatry. Adult Depressed Mood (Concurrent Review); (Initial Review)
InterQual 2015: BH: Adult Psychiatry. Adult Depressed Mood (Concurrent Review); (Initial Review)
InterQual 2015: BH: Adolescent Psychiatry. Adolescent Depressed Mood (Concurrent Review); (Initial Review)

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>97810- 97814</td>
<td>Acupuncture, 1 or more needles; with/without electrical stimulation</td>
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<td>96825-96828</td>
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