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Clinical Guideline

Guideline Number: PG109, Ver. 1

Clomipramine

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Clomipramine is FDA-approved for the treatment of Obsessive-Compulsive Disorder (OCD). OCD is a common disorder where a person has uncontrollable, recurring thoughts, and/or behaviors that he or she feels the urge to repeat over and over. The initial dose of clomipramine is 25 milligrams (mg) daily and can be increased gradually as tolerated over the first 2 weeks to 100 mg daily in divided doses. After the initial titration, it is recommended to wait 2-3 weeks between dosing adjustments to assess tolerability and effectiveness. The maximum dose of clomipramine is 250 mg a day.

Potential adverse reactions to clomipramine include suicidal ideation, dizziness, drowsiness, headache, weight gain, change in libido.

Note: The Plan may require that preferred medications be used first.

Definitions

"Obsessive-Compulsive Disorder (OCD)" is a common disorder where a person has uncontrollable, recurring thoughts, and/or behaviors that he or she feels the urge to repeat over and over.

Medical Necessity Criteria for Initial Authorization

1. The member has a diagnosis of Obsessive-Compulsive Disorder (OCD); ***and***
2. The member has had an inadequate treatment response, intolerance, or has a contraindication to at least TWO of the following:
    a. fluoxetine
    b. fluvoxamine
    c. sertraline
    d. paroxetine
    e. citalopram
    f. escitalopram
    g. venlafaxine
3. Clomipramine will be dosed within FDA approved limits or as recommended by case studies or clinical guidelines.
    a. If dosing outside normal limits, reviewers may consult with Medical Directors or other clinical resources to confirm appropriate dosing.

<u>If the above prior authorization criteria are met, clomipramine will be approved for 36 months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for 36 months will be granted if the member (still meets the initial criteria and) has chart documentation demonstrating a clinical improvement in symptoms since starting the requested medication:

1. The member's condition has improved or stabilized based upon the prescriber's assessment.

Table 1: Dosage and retreatment information

Indication	Initial dose	Subsequent dose	Retreatment	Additional Considerations
Obsessive-Compulsive Disorder (OCD)	25 mg daily and should be gradually increased during the first 2 weeks as tolerated to 100 mg in divided doses.	After initial titration, dosage can be increased over several weeks up to a maximum of 250 mg daily.	After initial titration, dosage can be increased over several weeks up to a maximum of 250 mg daily.	After initial titration, the total daily dose may be given once daily at bedtime to minimize daytime sedation.

Experimental or Investigational / Not Medically Necessary

Clomipramine for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Clomipramine HCL [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 26, 2021.
2. Micromedex® (electronic version). Drugs that treat OCD. IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed Feb 28, 2022.

Clinical Guideline Revision / History Information

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