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CMS LCD L35170 – OnabotulinumtoxinA (Botox®)
Effective February 22, 2026

The Centers for Medicare & Medicaid Services (CMS) recently issued updates to its Local Coverage Determination (LCD L35170) related to onabotulinumtoxinA (Botox®), effective February 22, 2026. AUGS Coding & Reimbursement Committee is carefully reviewing these changes and will provide future guidance through our Coding Fact Sheets. In the meantime, it is important to note CMS will now require **an objective assessment of OAB severity prior to initial treatment,** as well as a post-treatment objective assessment to determine success and again, prior to any and all retreatment with Botox. CMS is suggesting the use of an objective OAB scale for such documentation.

According to the LCD, Initial Botulinum Toxin Injections (BTIs) for OAB will be considered reasonable and necessary when the following requirements are met:

1. The documentation supports a diagnosis of refractory overactive bladder; AND
2. The OAB has been diagnosed by a history and physical exam and a urine analysis to rule out infection or blood in the urine; AND
3. There is moderate to severe OAB assessed by an objective scale*; AND
4. Conservative treatment for OAB has been tried but the OAB symptoms are refractory to a minimum of 12 weeks of standard of care treatment.
    - Conservative management which may consist of education of normal bladder function, self-care practices, behavioral modifications, stress management practices, manual physical therapy, and combination therapy; AND
    - Pharmacological therapy: anticholinergic or beta-3 adrenergic agonists (in absence of absolute contraindication to the medications).

**The objective assessment must be performed and documented at baseline, after each diagnostic procedure, and at each follow-up assessment using the same scale during each assessment, such as the Overactive Bladder Symptom Score (OABSS), International Prostate Symptom Score–Storage Subscore (IPSS-S), the modified Urgency Severity Scale (USS), and hypersensitive bladder (HSB).*

Initial Dosing Guidelines

1. The initial dose of onabotulinumtoxinA is a total dose of 100 Units per treatment session for Idiopathic OAB
2. The initial dose of onabotulinumtoxinA is a total dose of 100 – 200 Units per treatment for Neurogenic Detrusor Overactivity.

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Subsequent Botulinum Toxin Injections

Subsequent BTIs for OAB will be considered reasonable and necessary when the following requirements are met:

1. Documentation of informed clinical decision regarding repeat botulinum toxin injections; AND
2. Reassessment of the degree of persistent OAB and assessment of previous response to botulinum toxin; AND
3. Documentation of a positive response to the initial onabotulinumtoxinA injections.

Subsequent Dosing Guidelines

1. The subsequent dose of onabotulinumtoxinA is a total dose of 100 Units per treatment session for Idiopathic OAB
2. The subsequent dose of onabotulinumtoxinA is a total dose of 100 – 200 Units per treatment for Neurogenic Detrusor Overactivity.

Additionally, BTIs must not be given more frequently than every 12 weeks, regardless of diagnosis, unless specifically addressed in the LCD.

AUGS is actively seeking clarification from CMS, including engagement through partners such as ACOG and AUA. We will continue to monitor developments and provide additional guidance as further clarification becomes available via our Coding Fact Sheets and future newsletter alerts.