How Is OnabotulinumtoxinA Reimbursed For Chronic Migraine?

Impact Of FDA Approval And The New CPT Code

Effective January 1, 2013, physicians will be able to report the new CPT code 64615 when performing chemodenervation to treat chronic migraine. Headache Medicine specialists have used OnabotulinumtoxinA “off-label” as an efficacious treatment for headache prophylaxis for a number of years. The October 15, 2010 FDA approval of Botox “…to prevent headaches in adult patients with chronic migraine” followed the pooled results from the double-blind, randomized, placebo-controlled Phase 3 Research Evaluating Migraine Prophylaxis Therapy (PREEMT) 1 and 2 trials (Headache 2010; 50:921-936). PREEMT demonstrated that OnabotulinumtoxinA was an effective prophylactic treatment for chronic migraine. The PREEMT studies also defined the appropriate patient selection, injection sites, dosages and technique. It is likely that for reimbursement, insurers will monitor to document that the PREEMT protocol and injection paradigm targets were followed according to the published reports.

While specific fixed sites for the pericranial injections were established as an effective injection paradigm, as the treatment approach evolved, other sites corresponding to the location of pain and tenderness in an individual patient were added. A combination of 31 FSFD (fixed-site, fixed-dose) and FTP (follow-the-pain) injection protocol was found to be most optimal. A minimum dose of 155 U of Botox was administered across 7 specific head/neck muscles. An additional 40 U of OnabotulinumtoxinA could be administered at the physician’s discretion using a FTP strategy up to a maximum dose of 195 U administered to 39 sites. The protocol was repeated every 12 weeks for up to 5 treatment cycles. Those patients eligible for Botox must meet the IHS criteria for chronic migraine; specifically headaches ≥ 15 days per month for ≥ 3 months with headaches occurring on ≥ 8 days being classified as migraine headaches without aura or headaches that respond to migraine specific medications. While Botox is the first
and only medication FDA approved for the treatment of this group of chronic headache patients, it is likely that barriers will remain regarding the accessibility of OnabotulinumtoxinA for many patients. Below some basic considerations are listed.

1. Botox is expensive. The physician/practice expense for a 100 U vial is generally standardized at $525. Currently Medicare allows $5.48/U or $548 per vial. Private carriers reimburse different sums for a 100 U vial of Botox. Depending on different factors, contracted payments from insurers could range from $545 to $580 per vial. The physician charge to the patient may be considerably higher; based upon the practice fee schedule. In many parts of the country, there are practices that charge $2000 (or more) for a 100 U vial which would bring the cost of Botox for chronic migraine up to $4000, just for the medication. The differentiation between the allowable and actual patient charge thus becomes an additional expense to the patient. This added out of pocket burden, after the insurance contracted fee is reconciled, could be as expensive as $1000 - $2000. For this reason, some patients have been forced to initially decline treatment. It is also common for those patients to transfer their care to another headache specialist whose Botox fees better correlate with the insurance allowable charges. Other carriers such as United Health Care require the use of their own pharmacy to supply the Botox. To some practices, this could result in potential administrative difficulties in coordination of care. While the reimbursements from private insurance companies fall within a general range, various plans within the same insurance carrier may also have different reimbursement schedules. Despite the fact that the FDA has approved Botox for the treatment of chronic migraine, insurance companies are not required to cover the cost of the procedure or even include Botox in individual coverage.

2. For those physicians who are employed by a large health care system, the debits and credits of purchasing Botox are usually managed by the organization. For those doctors in private practice, that responsibility
should be managed by an employee who understands the precertification process for Botox. It is very important to verify benefits to determine if the plan covers Botox. As an aid, Allergan maintains a Botox Reimbursement Website; www.botoxreimbursement.us. An insurance provider must be enrolled with the Allergan program to use this tool. Not all providers are enrolled. If the patient’s insurance plan is enrolled, following input of diagnosis, number of units needed and the patient’s insurance information, Allergan will help verify benefits. This includes the coverage status for Botox, medical and pharmacy benefits, the co-pay and deductible. The website also has various reimbursement forms such as a template for a letter of medical necessity. Additional reimbursement information is also available on the website.

3. Basically every insurance plan does require pre-authorization. This usually includes the documentation of medical necessity. The diagnosis of “chronic migraine” must also be clearly defined in the physician’s medical records. The medication “J code” for Botox is J0585. The new CPT administration code 64615 will need to be included. Usually carriers request the physician’s medical records to verify the documentation of diagnosis. Some insurance carriers also require a Botox Prior Authorization Form be completed and attached to the medical records. Authorization may take up to a few days to 10 days or longer.

4. Some insurers may grant precertification, however they do not guarantee payment even after precertification. For example, on one of our patients, BlueCross BlueShield of Texas stated: “Based on the documentation submitted, 64612 64613 and J0585 for (botox) meets the medical policy criteria….However, predetermination of benefits does not guarantee payment...Benefits are always subject to other applicable requirements...”.

5. While evidence based medicine indeed can justify the use of Botox for chronic migraine, some carriers will require extensive documentation that treatment with other migraine preventive medications have failed. Many insurance precertification requirements only include “…adults who have tried and failed trials of at least 3 classes of migraine headache prophylaxis medication of at least 2 months (60 days) duration for each medication”.


These criteria are mandated even though none of the other listed medications are proven effective against chronic migraine and none are FDA-approved for the indication.

6. The physician also bills for an injection fee. The PREEMT criterion defines bilateral injections. Some carriers reimburse according to an injection fee per site; but the published treatment paradigm includes both left and right injections. Different practices charge different amounts for the injection fee. However, even if the physician charge were $450 per site ($900 for bilateral injections), the Medicare allowable is less. An estimated reimbursement for bilateral injections from private carriers is often in the ±$300 range. The literature estimates the cost of Botox therapy for chronic migraine at about $1300 to $1500 per treatment session. Again, those fees may be different according to a number of variables including the individual practice fee schedule and geography.

Although most practices currently using OnabotulinumtoxinA for chronic migraine are already familiar with many of the above issues, all practices involved in the use of Botox recognize the importance of carefully monitoring the debits and credits involved in treatment. Remember, in most instances, the cost of the medication is paid up front by the practice and reimbursement follows the claim. Also, once a 100 U vial of OnabotulinumtoxinA has been reconstituted, it must be injected or immediately stored in a refrigerator at 2-8 degrees C in the original vial (not a syringe) and used within 24 hours. Following treatment and submission of the claim to the insurance company, due diligence must be exercised to verify that the account is reconciled in a reasonable period of time. Accurate accounting is necessary to establish what payments are outstanding; both for the medication and the injection fee. A carrier’s prior authorization must include all the proper codes, a date range approval, the approved number of treatments and the authorization number. The number one thing any carrier scrutinizes is the physician’s documentation in the medical records. All criteria must be met for reimbursement. The PREEMT study and new CPT code (64615) for chemodenervation to treat chronic migraine is a major step forward in the treatment for a group of patients who had previously been excluded from
migraine prophylaxis trials because they were considered too highly disabled and treatment resistant. However, despite FDA approval, reimbursement patterns have not been completely elucidated.

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