First drug approved for tardive dyskinesia

By Mollie Durkin

**Approvals**

Valbenazine (Ingrezza), the first drug approved to treat adults with tardive dyskinesia, efficacy of the drug, which comes in capsule form, was demonstrated in a placebo-controlled trial of 234 participants. After six weeks, those who received the drug had improvement in the severity of abnormal involuntary movements compared to those who received placebo. Serious side effects include sleepiness and QT prolongation. The drug is contraindicated in patients with congenital long QT syndrome or with abnormal heartbeats associated with a prolonged QT interval. The drug was granted fast-track approval and priority review and designated as a breakthrough therapy.

Niraparib (Zejula) for the maintenance treatment of adults with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer whose tumors have completely or partially shrunk in response to platinum-based chemotherapy. The poly ADP-ribose polymerase inhibitor works by blocking an enzyme involved in repairing damaged DNA, potentially leading to death of cancerous cells. Safety and efficacy were studied in a placebo-controlled randomized trial of 553 patients. Median progression-free survival for patients with a germline BRCA mutation was 21 months for those taking the drug, compared to 5.5 months for those taking placebo. For patients without the mutation, median progression-free survival was 9.3 months on the drug compared to 3.9 months on placebo. Common side effects include anemia, thrombocytopenia, neutropenia, heart palpitations, nausea, constipation, vomiting, abdominal distention, mucositis, and diarrhea. Serious risks of the orphan drug, which received fast-track designation and priority review, include hypotension, hypertensive crisis, myelodysplastic syndrome/myeloid leukemia, and bone marrow suppression.

Dulipram (Dupixent) injection to treat adults with moderate-to-severe atopic dermatitis whose symptoms are not adequately controlled by topical therapies. The drug may be used alone or without or with or without corticosteroids. Safety and efficacy were established in three placebo-controlled trials of 2,119 adults. Overall, compared to those who received placebo, those who received the drug achieved a greater response and experienced a reduction in itch in 16 hours of treatment. Side effects include serious allergic reactions and eye problems, such as conjunctivitis and keratitis. The most common side effects include injection-site reactions, cold sores in the mouth or on the lips, and eye and eyelid inflammation.

Ocrelizumab (Ocrevus) to treat adults with relapsing forms of multiple sclerosis (MS) and primary progressive multiple sclerosis (PPMS). The drug, an intravenous infusion administered by a health care professional, is the first to be approved to treat PPMS. Efficacy was shown in two trials of about 1,610 participants with relapsing forms of MS, who were treated for 96 weeks. Compared to those treated with interferon beta-1a, patients who received ocrelizumab had reduced relapse rates and reduced worsening of disability. In a study of 772 participants with PPMS who were treated for at least 120 weeks, those receiving the drug had a longer time to worsening disability compared to those receiving placebo.

The drug may cause serious infusion-related reactions and may increase the risk for malignancies (particularly breast cancer). The most common side effect was upper respiratory tract infection in the trials of patients with relapsing MS, and those with PPMS most commonly experienced upper respiratory tract infection, skin infection, and lower respiratory tract infection. The drug application received priority review, fast-track designation, and breakthrough therapy designation.

**First-time generic approvals**

Sildenafil capsules (4 mg, 8 mg) to treat the signs and symptoms of benign prostatic hyperplasia. (Brand name: Kapralo)

Tazarotene cream (0.1%) to mitigate facial fine wrinkling, facial motility hyperpigmentation, and benign facial lentigines in patients who use comprehensive skin care and sunlight avoidance programs. (Brand names: Tazorac, Nuge)

Note: The FDA states that drugs are not always commercially available immediately after approval.

**Chronic care management codes worthwhile if done right**

By Margo Williams, MHA, CMPE

The uptake of billing the chronic care management (CCM) codes, which were introduced in 2015, has been mixed. Initially, most practices met the codes with skepticism because they seemed to be more trouble than they were worth. Many physicians, especially those in smaller practices, found that implementing CCM in their practice required hiring a dedicated person to manage the patients, which made it a risky venture.

However, most of those who have been using the codes have found that the reimbursement at least covers the cost of the additional care coordinator, that the codes have been profitable, and that they have improved outcomes for the participating patients. While much of this information is anecdotal, there is increasing evidence supporting the use of these codes if done smartly.

One of the biggest barriers to billing the CCM codes initially was the requirement that patients must agree to participate in person, which involved getting those with two or more chronic diseases into the office for a visit specifically to do that. However, new rules make it a little easier by allowing oral consent to participate in the program. Now a practice can call the patient, explain how the program works, and document the conversation in the chart.

It is important that clinical staff or physicians keep a record of time spent with participating patients, that the care coordination is properly documented and clinically necessary. In addition to keeping track of the time, such as using a log of some kind, they also need to make sure it is documented in the chart (in case of audit). In other words, time spent coordinating care or talking with the patient must be for a reason, such as following up after a dose change or lab result, scheduling testing, or returning a patient call, and not just for the sake of checking in.

The clinical staff providing the care coordination can be an existing staff person or, depending on the size of the practice and the number of patients who qualify, a new part-time or full-time hire. Clinical staff is defined by Current Procedural Terminology (CPT) as "a person who works under the supervision of a physician or other qualified health professional, and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service but does not individually report that professional service." Many commercial entities now offer CCM services on a contract basis to practices, but physicians should exercise caution before entering into such relationships. Practice staff know the patients and clinicians, as well as local subspecialists, facilities, and testing entities, best.

The table below shows the summary description and national average payment for each of the CCM codes.

<table>
<thead>
<tr>
<th>Code type</th>
<th>Summary description</th>
<th>National average payment</th>
</tr>
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<tbody>
<tr>
<td>Chronic care management, 99490</td>
<td>At least 20 min of clinical staff time/calendar month. Required elements: 2 or more chronic conditions expected to last &gt;12 mo or until death of patient; conditions place patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.</td>
<td>$42.71</td>
</tr>
<tr>
<td>Complex chronic care management, 99487</td>
<td>Includes criteria for 99490 as well as establishment or substantial revision of a comprehensive care plan, with moderate or high-complexity decision making, at least 60 min of clinical staff time/calendar month.</td>
<td>$93.67</td>
</tr>
<tr>
<td>Complex chronic care management, 99488</td>
<td>Includes criteria for 99487 as well as establishment or substantial revision of a comprehensive care plan, each additional 30 min/calendar month.</td>
<td>$47.01</td>
</tr>
</tbody>
</table>

It is important to note that the complex CCM codes are intended to be for those patients who really are complex. Most likely, it is expected that primary care physicians will not use these codes frequently, except perhaps in geriatrics or oncology or during those occasional months when something significant is going on with a patient that requires additional care from the team. Time spent personally by the physician may also be counted toward the clinical staff time (but not time spent during another billable service, such as an office visit).


Margo Williams, MHA, CMPE, is Senior Associate, Practice Management in ACP’s Department of Medical Practice, which provides members with resources related to practice management, compliance, and health information technology.