AAN Applauds Obama Administration’s Brain Research Initiative

The AAN supports the Obama administration’s new brain research initiative, set to launch in 2014 with $100 million in federal funding.

The initiative, announced by the White House in April, will be known officially as Brain Research Through Advancing Innovative Neurotechnologies, or “BRAIN” for short. The Obama administration has designated this as a grand challenge of the 21st century, much as the Human Genome Project was named a grand challenge of the 1990s.

“We are very excited by the administration’s much needed support for research into the brain diseases that devastate the lives of so many people,” said AAN President Timothy A. Pedley, MD, FAAN. “Our American Brain

Protect Your Patients Through Free FDA Safety Alerts

The AAN knows patient safety is a top concern of members, so it has partnered with the Physicians Desk Reference (PDR) Network to provide crucial Food and Drug Administration drug alerts free to members. All that is necessary is to sign up for the free online service, which delivers timely neurology-specific FDA-mandated patient safety drug alerts to your email.

The PDR Network (formerly the Health Care Notification Network) also provides the ability to submit experienced adverse events via the RxEvent website, which requires a separate registration.

More than 900 AAN members have signed up for the free service. Key benefits include:

- Improves patient safety and reduces physician liability
- Immediate notification of FDA alerts—no delays, paper, or mailbox clutter
- Convenient format to forward appropriate warnings to patients
- Endorsed by major liability carriers and medical societies
- Ability to register up to three other office staff to receive alerts
- Quick, convenient access for reporting adverse drug events

To learn more and enroll, visit www.aan.com/go/practice/patientsafety/drug.

June Webinars Help with Epilepsy and E/M Coding

The AAN will offer two Practice Management Webinars in June to help neurologists improve their coding skills.

“Coding Accurately for Epilepsy” will be presented live on Wednesday, June 5, from 12:00 p.m. to 1:30 p.m. ET. The deadline for registration is Tuesday, June 4. The webinar will be presented by Marc R. Nuwer, MD, PhD, FAAN, member of the AAN Coding Subcommittee and Section on Epilepsy.

Upon completion of the epilepsy webinar, participants should be able to:

- Differentiate when to use the appropriate EEG codes
- Determine diagnosis codes for epileptic and nonepileptic seizures

To learn more about June’s Practice Management Webinars, visit www.aan.com/go/practice/webinars.

Continue on page 13

Act Now to Avoid 2015 PQRS Penalties

Guideline Reviews Treatments for Parenchymal Neurocysticercosis

Brain Health Fair Attracts San Diego Residents

Continued on page 21
The 2013 AAN Annual Meeting received major media coverage from such outlets as NEWS BRIEFS head injury or concussion; the possibility that migraine with aura may lead to heart wide range of other research, including the link between diet soda and depression; While the sports concussion guideline made the biggest splash, the media covered a conference on the sports presented at the Annual Meeting, including the press Safety Alerts and E/M Coding.

**TABLE OF CONTENTS**

<table>
<thead>
<tr>
<th>COVER</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAN Applauds Obama Administration’s Brain Research Initiative</td>
</tr>
<tr>
<td>Protect Your Patients Through Free FDA Safety Alert</td>
</tr>
<tr>
<td>June Webinars Help with Epilepsy and E/M Coding</td>
</tr>
</tbody>
</table>

**PRACTICE MANAGEMENT**

| 4 | Act Now to Avoid 2015 PQRS Penalty |
| 12 | New Issues of Neurology: Clinical Practice, Neurology Now Available |
| 12 | Are You Participating in the CMS Bundled Payments Initiative? |

**MEETING**

| 14 | Guideline Reviews Treatments for Parenchymal Neurocysticercosis |

**PRESIDENT’S COLUMN**

| 3 | Annual Meeting, Neurology on the Hill Demonstrate Ideals of the AAN |
| 3 | Annual Meeting, Neurology on the Hill Demonstrate Ideals of the AAN |

**GUIDELINES**

| 22 | Thank you to 2011–2013 Academy Leaders |
| 29 | DATES AND DEADLINES |
| 30 | CAREER OPPORTUNITIES |

**NEWS BRIEFS**

The 2013 AAN Annual Meeting received major media coverage from such outlets as the New York Times, Wall Street Journal, USA Today, Los Angeles Times, TIME magazine, Chicago Tribune, Newsday, CNN, National Public Radio, and many others. While the sports concussion guideline made the biggest splash, the media covered a wide range of other research, including the link between diet soda and depression; blood pressure drugs and dementia risk; lesions revealed by brain imaging after mild head injury or concussion; the possibility that migraine with aura may lead to heart attack or blood clots in women; and a new add-on drug that may improve memory in people with moderate Alzheimer’s disease.

**PUBLIC POLICY**

| 14 | Capitol Hill Report |
| 17 | Neuro Health Policy Fellowship Coming |

**CME AND TRAINING**

| 16 | UCNS Celebrates 10 Years of Growth |
| 16 | UCNS Fellowship Accreditation Applications Due June 1 |
| 17 | Latest Continuum Audio Offers Expert Discussion on Epilepsy |

**AMERICAN BRAIN FOUNDATION**

| 18 | Paying It Forward |
| 19 | Brain Health Fair Attracts San Diego Residents |
| 19 | Donor Recognition |

**MEMBERSHIP**

| 22 | Thank you to 2011–2013 Academy Leaders |

**GUIDELINES**

| 14 | Guideline Reviews Treatments for Parenchymal Neurocysticercosis |

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**ANNUAL MEETING, NEUROLOGY ON THE HILL**

**TOPIC OF THE MONTH**

**SPECIAL REPORT**

**PRESIDENT’S COLUMN**

**RESIDENT’S COLUMN**

**MEMBERSHIP**

**PRACTICE MANAGEMENT**

**AAN APPLAUDS OBAMA ADMINISTRATION’S BRAIN RESEARCH INITIATIVE**

**NEWS BRIEFS**

I'm happy to report we had a very successful Annual Meeting in San Diego. Our attendance was the third highest in our history, new neurologic research was strongly displayed, and the various education programs were well-attended.

The first big event of the Annual Meeting was the Brain Health Fair, which was held on Saturday just as the meeting was getting underway. Nearly 2,000 residents of the San Diego area joined us to learn more about brain disease. Several dozen AAN members volunteered their time to present classes on some of the more prevalent neurologic disorders. The event attracted many families with children, and the fair also had some fun educational activities for youngsters. This is the third Brain Health Fair sponsored by the American Brain Foundation at the Academy’s Annual Meeting and it is proving to be a very successful way to reach out to the public, informing them of the latest research advances in brain disease while demonstrating the vital role that neurologists play in health care.

There was considerable interest in our new guideline “Update: Evaluation and Management of Concussion in Sports.” Lead co-authors Christopher C. Giza, MD, and Jeffrey S. Kutcher, MD, briefed the media, and the story was picked up widely by leading news publications, including the New York Times, USA Today, the Washington Post, the Los Angeles Times, Business Week, the San Francisco Chronicle, the Baltimore Sun, US News & World Report, the Boston Globe, the Philadelphia Inquirer, the Houston Chronicle, and Forbes, as well as National Public Radio, the Huffington Post, Bloomberg News, the major US television networks, and San Diego media. Within 72 hours after publication, the guideline was accessed over 40,000 times at Neurology.org. Publication of the guideline was accompanied by the free AAN Concussion Quick Check, a mobile phone app that helps non-physicians identify concussion; summaries of the guideline for clinicians, patients and families, coaches, and athletic trainers; and other resources you can find at www.aan.com/concussion. The AAN Board of Directors also approved an updated legislative position statement on the topic. A radio public service announcement will be broadcast in major markets, and a podcast interview with the lead authors will soon be available as well.

The Annual Meeting also gave AAN leadership and staff the opportunity to meet personally with members who have been alarmed and upset by reimbursement cuts for nerve conduction studies, EMGs, and intraoperative monitoring approved by the Centers for Medicare and Medicaid Services (CMS). In addition to these cuts, practices also have to cope with a new 2-percent Medicare cut due to sequestration. We scheduled a number of opportunities at the San Diego Convention Center where members could discuss these cuts, including an open microphone session following the Business Meeting. While all of us are understandably frustrated by these actions in Washington, it is important to recognize that the Academy has been working hard on members’ behalf to try to change CMS’s position. The AAN has created a number of excellent resources to help guide members through this difficult period, and I urge you to review them at www.aan.com/go/practice/coding.

I want to assure you that the Academy is not retreating one inch in its fight for fair reimbursement for neurologists. At the end of April, I joined more than 140 AAN members who went to Washington, DC, for our annual Neurology on the Hill event. We met with members of Congress and their staffs to urge them to cosponsor legislation that would provide the same increase to Medicare reimbursement for neurologists and other specialists that internal medicine subspecialties received in the Affordable Care Act. Our members also urged Congress to rescind the flawed Medicare Sustainable Growth Rate and establish a stable physician fee schedule that can be relied on.

I enjoyed meeting many members at the Annual Meeting and subsequently advocating with them in Washington. These two events exemplify the intrinsic value of the Academy: to help us update our knowledge to improve our skills as practitioners, and to advocate for the interests of our patients and our profession. Participating in these activities is invigorating and reaffirming, particularly given the many challenges we face. I encourage you to deepen your involvement with the AAN and make the most out of your membership and the many benefits it provides.

Timothy A. Pedley, MD, FAAN
President, AAN

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There was a great deal of media interest generated by the science and research presented at the Annual Meeting, including the press conference on the sports concussion guidelines.
Act Now to Avoid 2015 PQRS Penalty

Members should participate in reporting Physician Quality Reporting System (PQRS) quality measures now or risk penalties from the Centers for Medicare & Medicaid Services in 2015. Each year, there are revisions to measures and new measures are added. Members are encouraged to develop a plan on how to participate in 2013 and avoid the penalty for 2015.

According to CMS, eligible professionals and group practices who do not report data on PQRS quality measures for covered professional services during the 2013 program year will face a payment adjustment beginning in 2015. Eligible professionals and group practices receiving a PQRS payment adjustment in 2015 will be paid 1.5 percent less than the Physician Fee Schedule (PFS) amount for services rendered January 1 to December 31, 2015.

The applicable percent for payment adjustments under PQRS are as follows:

- 1.5-percent adjustment in 2015 (eligible professional will receive 98.5 percent of his/her allowed Medicare Part B PFS amount for covered professional services that would otherwise apply to such services)
- 2.0-percent adjustment in 2016 and subsequent years (eligible professional will receive 98 percent of his/her allowed Medicare Part B PFS amount for covered professional services that would otherwise apply to such services)

For the 2013 PQRS program, CMS has 6-month and 12-month reporting options. The 6-month reporting option applies only to measures which are in a measures group and reported via a registry (i.e., Parkinson’s disease, dementia, sleep apnea). The 12-month reporting option would be retained for individual measures which are reported either via a registry or claims (i.e., epilepsy).

To learn more about how to participate in PQRS and avoid these penalties, visit www.ama.com/go/practice/pay/pqrsguide. Additional information is provided in the February 2013 Neurology® Clinical Practice article “Quality Measures for Neurologists.”

There are more than 300 PQRS measures, including general measures that apply to patients of all conditions. Some may be reported by claims, and others must be reported via a registry. Measures that pertain to neurologists include:

- Epilepsy (3 by claims)
- Stroke (4 by claims, 6 by registry)
- Sleep apnea (4 by registry)
- Parkinson’s disease (6 by registry)
- Back pain (4 by registry or claims)
- Dementia (9 by registry or claims)

IN THE TREATMENT OF RELAPSING FORMS OF MS
DON’T LET MS DEFINE YOUR PATIENTS

WARNING: HEPATOTOXICITY AND RISK OF TERATOGENICITY

Hepatotoxicity - Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for teriflunomide because recommended doses of teriflunomide and leflunomide result in a similar range of plasma concentrations of teriflunomide. Concomitant use of AUBAGIO with other potentially hepatotoxic drugs may increase the risk of severe liver injury. Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy. Monitor ALT levels at least monthly for six months after starting AUBAGIO. If drug induced liver injury is suspected, discontinue AUBAGIO and start an accelerated elimination procedure with cholestyramine or charcoal. AUBAGIO is contraindicated in patients with severe hepatic impairment. Patients with pre-existing liver disease may be at increased risk of developing elevated serum transaminases when taking AUBAGIO.

Risk of Teratogenicity - Based on animal data, AUBAGIO may cause major birth defects if used during pregnancy. Pregnancy must be excluded before starting AUBAGIO. AUBAGIO is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during AUBAGIO treatment or prior to the completion of an accelerated elimination procedure after AUBAGIO treatment.

Please see additional Important Safety Information and Brief Summary of Full Prescribing Information on the following pages.
FOCUS ON EVERYDAY

AUBAGIO® (teriflunomide)—a once-daily oral therapy for relapsing forms of MS

INDICATION
AUBAGIO® (teriflunomide) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

IMPORTANT SAFETY INFORMATION

Hepatotoxicity—AUBAGIO is contraindicated in patients with severe hepatic impairment and in patients taking leflunomide. Severe liver injury, including fatal liver failure, has been reported in patients treated with leflunomide, which is indicated for rheumatoid arthritis. Teriflunomide is the principal active metabolite of leflunomide. A similar risk would be expected for teriflunomide because recommended doses of teriflunomide and leflunomide provide similar plasma concentrations of teriflunomide. Obtain transaminase and bilirubin levels within 6 months before starting AUBAGIO; monitor ALT levels at least monthly for 6 months after starting AUBAGIO. Patients with preexisting liver disease may be at increased risk of elevated serum transaminases when taking AUBAGIO. Patients with preexisting acute or chronic liver disease, or those with serum alanine aminotransferase (ALT) >2 times the upper limit of normal (ULN) before starting treatment, should not normally be treated with AUBAGIO. In clinical trials, if ALT elevations >3 times the ULN on 2 consecutive tests, AUBAGIO was discontinued and patients underwent accelerated elimination. Consider additional monitoring if coadministering AUBAGIO with other potentially hepatotoxic drugs because of increased risk of severe liver injury; monitor patients who develop symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine). If drug-induced liver injury is suspected, discontinue use of AUBAGIO, because of increased risk expected for teriflunomide; therefore, stop treatment and use accelerated elimination if a severe skin reaction develops.

Safety Profile

Risk of Teratogenicity—AUBAGIO is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Based on animal data, AUBAGIO may cause major birth defects if used during pregnancy. Before starting therapy, pregnancy must be excluded, use of reliable contraception confirmed, and the patient fully counseled. Patients having delayed onset of menses or other reason to suspect pregnancy should immediately notify their physician and be apprised of the potential hazards to the fetus. If the patient is pregnant or wishes to become pregnant, treatment should be discontinued immediately, followed by accelerated elimination until plasma concentrations of <0.02 mcg/mL are verified. It is not known whether AUBAGIO passes into breast milk; patients should be counseled on whether they should take AUBAGIO or breastfeed—they should not do both at the same time. Women who become pregnant while taking AUBAGIO should enroll in the AUBAGIO Pregnancy Registry to monitor fetal outcomes, by calling 1-800-745-4447, option 2. AUBAGIO is eliminated slowly from the plasma. Without accelerated elimination, reaching plasma concentrations of <0.02 mcg/mL takes an average of 8 months or, in some patients, up to 2 years. Accelerated elimination may cause disease activity to return in patients who were responding to AUBAGIO treatment. AUBAGIO is detected in human semen. Men not wishing to father a child should use reliable contraception to minimize possible risk. Men wishing to father a child should discontinue AUBAGIO and undergo accelerated elimination until plasma concentrations of <0.02 mcg/mL are verified.

Additional Safety Information

Decreases in white blood cell counts, mainly of neutrophils and lymphocytes, and platelets have been reported in clinical studies of AUBAGIO. Obtain a complete blood cell count within 6 months before starting treatment. Further monitoring should be based on symptoms suggestive of bone marrow suppression. AUBAGIO is not recommended for patients with severe immunodeficiency, bone marrow disease, or severe uncontrolled infections. Treatment in patients with infection(s), acute or chronic, should not be started until the infection(s) is resolved. Medications such as teriflunomide have immunosuppressive potential; patients may therefore be more susceptible to infections. The risk of malignancy, particularly lymphoproliferative disorders, is increased with some immunosuppressive medications. Vaccination with live vaccines is not recommended. Tuberculosis has been observed in clinical studies of AUBAGIO. Before starting treatment, screen patients for latent tuberculosis infection with a tuberculin skin test. Peripheral neuropathy, including polyneuropathy and mononeuropathy, has been reported with AUBAGIO. Age >60 years, concomitant neurotoxic medications, and diabetes may increase the risk. If peripheral neuropathy is suspected, consider discontinuing treatment and performing accelerated elimination. Transient acute renal failure and treatment-emergent hyperkalemia, as well as increased renal uric acid clearance, have been reported with AUBAGIO. Monitor renal function and potassium if symptoms of acute renal failure or hyperkalemia appear. Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported rarely in rheumatoid arthritis patients receiving leflunomide, with a similar risk expected for teriflunomide; therefore, stop treatment and use accelerated elimination if a severe skin reaction develops.

Efficacy

ONCE-DAILY ORAL DOSING

AUBAGIO is available in 14 mg and 7 mg tablets.

Please see Brief Summary of Full Prescribing Information, including boxed WARNING.
**AUBAGIO® (teriflunomide)—a once-daily oral therapy for relapsing forms of MS**

**EFFICACY**

**SAFETY PROFILE**

**ONCE-DAILY DOSING**

**FOCUS ON EVERY DAY**

---

**Efficacy demonstrated in the 2-year pivotal trial.**

- Statistically significant reductions in AUBAGIO 14 mg in annualized relapse rate (ARR), risk of sustained disability progression, and MRS total lesion volume (TLV)
- The 7 mg dose of AUBAGIO achieved statistically significant reductions in ARR and MRS TLV but not in sustained disability progression.

**SAFETY PROFILE informed by >1300 patient-years of exposure in Phase II and TEMSO Phase III trials.**

- The most frequent adverse reactions (incidence ≥10% and ≥2% greater than placebo) with AUBAGIO 14 mg, 7 mg, and placebo, respectively, were alanine aminotransferase (ALT) increases (14%, 12%, and 7%), alopecia (10%, 13%, and 3%), diarrhea (18%, 15%, and 9%), influenza (12%, 10%, and 9%), nausea (14%, 9%, and 7%), and paresthesia (10%, 9%, and 8%).

- Similar proportions of patients in the AUBAGIO 14 mg and 7 mg and placebo groups had serious adverse events (AEs) (15.9%, 14.1%, and 12.8%, respectively).

- Overall discontinuation due to AEs was 10.9% with AUBAGIO 14 mg, 9.8% with AUBAGIO 7 mg, and 8.1% with placebo.

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**ONCE-DAILY oral dosing**

- Once-daily tablet can be taken at any time, with or without food.

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**AUBAGIO® (teriflunomide) tablets for oral administration**

**Rx Only**

**WARNING: HEPATOTOXICITY and RISK OF TERATOGENICITY**

**Hepatotoxicity**

Severe liver injury including total liver failure has been reported in patients treated with teriflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for teriflunomide because it is chemically related to leflunomide. Postmarketing data are also consistent with a similar risk in patients with psoriatic arthritis treated with teriflunomide. In postmarketing experience, patients with active chronic liver disease, or those with severe liver function impairment, who are treated with teriflunomide, or patients with a history of severe liver impairment, should not be treated with AUBAGIO. AUBAGIO is contraindicated in patients with active chronic liver disease (see Contraindications (4.2)).

In placebo-controlled trials, AUBAGIO 14 mg was no different overall in the increase in serious or fatal infections and no greater than placebo. However, in patients with active chronic liver disease or with severe liver impairment, or patients with active chronic hepatitis C, there is no experience to date with AUBAGIO treatment.

**Bone Marrow Effects/Immunosuppression Potential/Infections**

- Terminal half-life for teriflunomide is 17–19 days. About 95% of teriflunomide is metabolized in the liver, and the remaining 5% is excreted unchanged in the urine. About 90% of teriflunomide is excreted in the urine. In adult patients, teriflunomide is eliminated primarily in the urine, with elimination half-life of approximately 17 days. Teriflunomide is not removed by hemodialysis or peritoneal dialysis. The plasma drug concentration is reduced by 1% to 3% per day by continuous ambulatory peritoneal dialysis or by hemodialysis.

- Due to the potential for immunosuppression, patients with a history of cancer should not be treated with AUBAGIO. AUBAGIO is contraindicated in patients with a history of malignancy (see Contraindications (4.2)).

- Concurrent use of AUBAGIO with high-dose corticosteroids, other immunosuppressants, or antiproliferative drugs is contraindicated.

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**INDICATIONS AND USAGE**

AUBAGIO® is indicated for the treatment of patients with relapsing forms of multiple sclerosis (see Clinical Studies (14) in the full prescribing information).

**DOSAGE AND ADMINISTRATION**

- The recommended dosage of AUBAGIO 7 mg or 14 mg once daily orally can be taken with food or with an empty stomach.

- Monitoring to assess safety:
  - Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy.
  - Obtain ALT levels at least monthly for six months after starting AUBAGIO (see Warnings and Precautions (5.3)).
  - Obtain a complete blood count (CBC) with white blood cell differential and platelet count within 6 months before initiation of treatment with AUBAGIO. Further monitoring should be based on signs and symptoms of infection (see Warnings and Precautions (5.3)).
  -Prior to initiating AUBAGIO, consider patients with a history of tuberculosis infection, human immunodeficiency virus (HIV) infection, or other conditions that may involve bacillus Calmette-Guérin (BCG) vaccine (see Warnings and Precautions (5.3)).

**Dose Titration**

- AUBAGIO is titrated down to 7 mg orally daily, except in patients currently taking leflunomide. For patients currently taking leflunomide, patients should discontinue leflunomide and undergo an accelerated elimination procedure (see Use in Specific Populations (8.1) and Precautions (5.3) and Administration and Dosage (3.4)).

- Obtain serum transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy (see Warnings and Precautions (5.3)).

**CONTRAINDICATIONS**

- AUBAGIO is contraindicated in patients who are pregnant or women of childbearing potential who are not using reliable contraception. If this drug is used during pregnancy, or if the patient becomes pregnant while taking AUBAGIO, the patient should be referred to an obstetrician/gynecologist, preferably one with experience in reproductive toxicity, for further evaluation and counseling (see Contraindications (4.2), Use in Specific Populations (8.1), and Warnings and Precautions (5.3)).

- Use in Specific Populations (8.1) and Warnings and Precautions (5.3) must be considered. Use in women who are lactating is not recommended.

- Use in women who are lactating is not recommended.

- Use in women who are breast-feeding is not recommended.

- Use in women who are breast-feeding is not recommended.

**WARNINGS AND PRECAUTIONS**

**Risk of Teratogenicity**

- Teriflunomide may cause major birth defects if used during pregnancy. Pregnancy must be excluded before starting AUBAGIO. AUBAGIO is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during AUBAGIO treatment or prior to the completion of an accelerated elimination procedure after AUBAGIO treatment (see Contraindications (4.2), Warnings and Precautions (5.2), and Use in Specific Populations (8.1)).

**1. INDICATIONS AND USAGE**

AUBAGIO® is indicated for the treatment of patients with relapsing forms of multiple sclerosis (see Clinical Studies (14) in the full prescribing information).

**2. DOSAGE AND ADMINISTRATION**

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**3. CONTRAINDICATIONS**

AUBAGIO® is contraindicated in patients who are pregnant or women of childbearing potential who are not using reliable contraception. If this drug is used during pregnancy, or if the patient becomes pregnant while taking AUBAGIO, the patient should be referred to an obstetrician/gynecologist, preferably one with experience in reproductive toxicity, for further evaluation and counseling (see Contraindications (4.2), Use in Specific Populations (8.1), and Warnings and Precautions (5.3)).

**4. CONTRAINDICATIONS**

- AUBAGIO is contraindicated in patients who are pregnant or women of childbearing potential who are not using reliable contraception. If this drug is used during pregnancy, or if the patient becomes pregnant while taking AUBAGIO, the patient should be referred to an obstetrician/gynecologist, preferably one with experience in reproductive toxicity, for further evaluation and counseling (see Contraindications (4.2), Use in Specific Populations (8.1), and Warnings and Precautions (5.3)).

**5. WARNINGS AND PRECAUTIONS**

**5.1 Hepatotoxicity**

Severe liver injury including total liver failure and/or death has been reported in some patients treated with leflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for teriflunomide because it is chemically related to leflunomide. Postmarketing data are also consistent with a similar risk in patients with psoriatic arthritis treated with teriflunomide. In postmarketing experience, patients with active chronic liver disease, or those with severe liver function impairment, who are treated with teriflunomide, or patients with a history of severe liver impairment, should not be treated with AUBAGIO. AUBAGIO is contraindicated in patients with active chronic liver disease (see Contraindications (4.2)).

In placebo-controlled trials, AUBAGIO 14 mg was no different overall in the increase in serious or fatal infections and no greater than placebo. However, in patients with active chronic liver disease or with severe liver impairment, or patients with active chronic hepatitis C, there is no experience to date with AUBAGIO treatment. Further monitoring should be based on signs and symptoms of potential liver injury.

**Risk of Infection / Tuberculosis Screening**

- Administration of 50 g oral activated charcoal powder every 12 hours for 11 days. If infection(s) does not resolve, if a patient develops a serious infection consider suspending treatment with AUBAGIO. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved. If a patient develops a serious infection consider suspending treatment with AUBAGIO. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved. If a patient develops a serious infection consider suspending treatment with AUBAGIO. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved. If a patient develops a serious infection consider suspending treatment with AUBAGIO. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved. If a patient develops a serious infection consider suspending treatment with AUBAGIO. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved."
However, one fatal case of klebsiella pneumonia sepsis occurred in a patient taking teriflunomide 14 mg for 1 year. Fatal infections have been reported in the post-market setting, in patients receiving teriflunomide, especially in patients with severe, life-threatening, or chronic infections. The risk of severe infections was increased in patients with multiple sclerosis, as compared with patients taking placebo. There was an increased incidence of serious infections, especially pneumonia and aspergillosis. Most of the infections occurred in patients with serious underlying conditions (e.g., diabetes mellitus, cancer, and chronic kidney disease). In placebo-controlled studies, treatment-emergent infections (all types) in patients treated with teriflunomide 7 mg, teriflunomide 14 mg, and placebo were 25%, 35%, and 15%, respectively. In study 1, a 1-year, placebo-controlled clinical study in 1086 RMS patients treated with teriflunomide 7 mg (n = 355), teriflunomide 14 mg (n = 356), or placebo (n = 375), the percentage of patients with at least one infection was 14% for teriflunomide 7 mg, 22% for teriflunomide 14 mg, and 9% for placebo. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the incidence of adverse reactions observed in the clinical trials of another drug and may not reflect the rates observed in the clinical practice.

Table 1 Adverse Reactions in Study 1 [occurring in ≥ 2% of patients, and reported for teriflunomide 7 mg or 14 mg versus 0% for placebo in the full prescribing information].

Table 1 Adverse Reactions in Study 1 (occurring in ≥ 2% of patients, and reported for teriflunomide 7 mg or 14 mg versus 0% for placebo in the full prescribing information)
Neurology: Clinical Practice, Neurology Now Available

The April issue of Neurology® Clinical Practice was mailed recently to US subscribers of Neurology. Be sure to check out the insightful articles about neurologic practice today, including three Eye on Practice papers dedicated to navigating the changing landscape of health care delivery and payment:

Editorial: The Revolution of Practice By John R. Corboy, MD, FAAN

Neurologists and Technology: The Changing ‘Facebook’ of Practice By Daniel C. Potts, MD, MD, and Anna D. Hohler, MD

How to Select and Implement an Electronic Health Record in a Neurology Practice By Allison L. Weathers, MD, and Gregory J. Esper, MD, MBA

The Neurologist as a Medical Home Neighbor
By Daniel B. Hoch, MD, PhD; Mark C. Homonnoff, MD; Heidi Mowassad, MD; James H. Cohen, MD, FAAN; Gregory J. Esper, MD, MBA; Amanda Becker; and Neil A. Buis, MD, FAAN

Neurology: Clinical Practice has increased its publication to six times in 2013. It is available in print (for US members only), online, and for the iPad®. Visit www.aan.com/go/library/clinicalpractice for more information.

Professional soccer star Tim Howard discusses the challenges he’s faced living with Tourette’s syndrome in the April/May issue of the AAN’s patient magazine Neurology Now®.

Other articles focus on the AAN’s recent sports concussion guideline, the tragic link between chronic pain and suicide, how movement and dance helps some people with Parkinson’s disease reconnect with their bodies, and the recent “Choosing Wisely” report on testing, procedures, and treatments with limited value that physicians and patients should consider avoiding.

For more information about Neurology Now, the AAN’s free bimonthly magazine for neurology patients, their families, and caregivers, visit www.neurologynow.org. AAN members may receive up to 30 free copies of each issue to distribute to patients. To adjust the number of copies of Neurology Now received in your office, contact AAN Member Services at (800) 879-1960, or update your member profile at www.aan.com/view/profile.

New Issues of Neurology: Clinical Practice, Neurology Now Available

Are You Participating in the CMS Bundled Payments Initiative?

According to the Centers for Medicare and Medicaid Services (CMS), more than 500 hospitals and health systems will take part in the Bundled Payment for Care Improvement (BPCI) initiative in 2013.

Bundled payment is a single payment for all services needed during a defined episode of care. BPCI participants were able to select from 48 episodes of care but had to define the episodes and come up with a target price or prospective bundled payment amount based on CMS data.

The hospital system where AAN member Joel M. Kaufman, MD, FAAN, works was selected to participate in the BPCI initiative. “Rhode Island, The Miriam, and Newport Hospitals are all looking to participate in the BPCI program,” said Kaufman. “At this point, we are looking at all 48 bundles in Model 2, including stroke. Potential savings are primarily in post-discharge areas. Neurologists will have a role in making sure patients are diagnosed accurately, go home or to rehab appropriately, and that there is good follow-up to prevent readmissions or ED visits. Even for other bundles, identifying cognitive or other issues is critical. “One important aspect of the program is that savings are shared with clinical partners. Neurologists should not be shy in articulating their role in making these programs a success and how this role will be recognized financially.”

The Academy seeks more information from neurologists who participate in new payment models like bundled payments, ACOs, or patient-centered medical homes. If you would like to share your experiences, contact Karolina Craft at kcraft@aan.com. More details about BPCI are available at innovation.cms.gov/initiatives/bundled-payments.

June Webinars Help with Epilepsy and E/M Coding

Continued from cover

• Structure their documentation to comply with federal standards of these patient encounters
• Recognize the standards for recording and reporting time
• "E/M: Minimize Mistakes, Maximize Reimbursement" will be presented by Peter D. Donofrio, MD, FAAN, member of the AAN Coding Subcommittee, live on Tuesday, June 25, from 12:00 p.m. to 1:30 p.m. ET. The registration deadline is Monday, June 24.

Upon completion of the E/M webinar, participants should be able to:
• Appropriately code patient visits
• Gain confidence in coding and billing for complex E/M services
• Master medical decision making
• Properly use the Academy’s E/M templates
• Prepare their practice and discover ways to avoid audits

Both webinars begin with 60 minutes of lecture followed by 30 minutes of questions and answers.

The cost to participate in the 2013 webinars is $149 for the first and $50 for each additional webinar—more than 25 percent off the pricing for nonmembers. The bundling discount is applicable only when multiple webinars are purchased in the same transaction. Participants are charged per phone line, so additional staff can listen in with no extra cost. All registrants will have access to both the live and recorded options for the webinar(s) they purchase. Slides are included with all webinar purchases.

For more information, including dates and speakers for 2013 webinars, visit www.aan.com/view/pmew13 or contact Elizabeth Bradshaw at ebradshaw@aan.com.

Remember to Register for May Webinar

Time still remains to register for the AAN webinar “Remaining Relevant in the Changing Health Care Payment and Care Delivery Systems,” offered on May 14, 2013, from 12:00 p.m. to 1:30 p.m. ET. The deadline for registration is Monday, May 13. The webinar will be presented by Daniel B. Hoch, MD, PhD, FAAN, member of the Practice Management & Technology Subcommittee. Register at www.aan.com/view/pmew13.

Access the sports concussion guideline, resources, and app at aan.com/concussion.
Guideline Reviews Treatments for Parenchymal Neurocysticercosis

A combination of albendazole and a corticosteroid can effectively treat neurocysticercosis, a tapeworm CNS infection that is the most preventable cause of epilepsy, according to the AAN’s “Evidence-based Guideline: Treatment of Parenchymal Neurocysticercosis,” published in the April 9, 2013, issue of Neurology®.

Neurocysticercosis is a CNS infection of the brain or spinal cord caused by the tapeworm Taenia solium. The tapeworm can also cause taeniasis, an infection of the intestines. If the infection does not spread beyond the intestines, the patient may be asymptomatic for years. If the infection spreads to the CNS, it can cause seizures or epilepsy, or encephalopathy and other symptoms. Infections have occurred mostly in developing countries, but they are now on the rise in developed countries, including the United States. About 2 million people worldwide have epilepsy from this tapeworm, which, according to the World Health Organization, is the most common preventable epilepsy in the developing world.

“It is critical for neurologists and other providers to recognize this infection,” said lead author Karen Roos, MD, FAAN. “This previously rare disease in the United States is increasingly prevalent, and the infection and its sequelae are preventable.”

Read the guideline and access PDF summaries for clinicians and patients, a slide presentation, and a clinical example at www.aan.com/go/practice/guidelines. For more information, contact Julie Cox at jcox@aann.com or (612) 928-6069.

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Capitol Hill Report

Capitol Hill Report presents regular updates on legislative and regulatory actions and how the Academy ensures that the voice of neurology is heard on Capitol Hill. It is emailed to US members twice monthly and is posted at www.aan.com/go/advocacy/hillreport. Below are some recent highlights.

SGR Fire Sale?

Mike Amery reported that the Congressional Budget Office had lowered the projected cost of a complete repeal of the Medicare Sustainable Growth Rate (SGR) formula from nearly $300 billion over ten years to just $138 billion. This could be the year when the SGR really is eliminated. “Just $138 billion” is still a lot of money, but the term “fire sale” keeps being used by members of Congress on both sides of the aisle. The AAN is working with our physician colleagues across the Hill to see if we can eliminate the SGR once and for all.

AAN Meets with CMS for Update on Refinement Panel Request

Daneen Green met with Jonathan Blum, the director of Medicare for the Centers for Medicare and Medicaid Services (CMS), to reiterate our request to send the new NCS and EMG codes to refinement and for a panel for further review. Blum informed her that a decision will be made within the next month and that the AAN will receive a notification letter during that timeframe if the codes are accepted.
UCNS Celebrates 10 Years of Growth

The United Council for Neurologic Subspecialties (UCNS) reached another milestone by celebrating its 10th anniversary this year.

“Taking on the mission of developing neurologic subspecialties was met with skepticism and concern,” said UCNS Chair Paul M. Vespa, MD, FCCM, FAAN. “As with most novel, pioneering endeavors, the UCNS was risky, but the vision of modern neurology was clear. Luckily, we had visionary leaders in the early years, such as Dr. Stephen Sergay, who believed that UCNS could play an important role in helping neurologists assume leadership roles in the treatment of patients.”

Since its incorporation in 2003, UCNS has grown steadily. UCNS has now recognized nine subspecialties and accredited 108 fellowship programs in 28 states and a Canadian province. The first certification exams were offered in 2006. As of early 2013, 1,545 physicians have been certified in eight subspecialties. They practice in 47 states as well as Puerto Rico, the District of Columbia, and four Canadian provinces.

“Over the years, UCNS has benefitted from the generous financial support of its parent organizations, particularly the American Academy of Neurology,” Vespa said. “While there are challenges ahead, we look forward to the next 10 years.”

UCNS Fellowship Accreditation Applications Due June 1

Fellowship programs seeking accreditation by the United Council for Neurologic Subspecialties should apply by June 1, 2013. Applications submitted by June 1 will be reviewed in the fall. Approved programs will be accredited effective December 1, 2013.

UCNS offers accreditation in nine subspecialties. To view program requirements and download an application, visit www.ucns.org. For more information, contact Amanda Carpenter at acarpenter@ucns.org or (612) 928-6065.

Latest Continuum Audio Offers Expert Discussion on Epilepsy

The latest edition of Continuum® Audio features series Co-Associate Editor Ralph Juszczowicz, MD, FAAN, leading a panel of experts in discussions involving the diagnosis, management, and treatment of epilepsy.

The AAN’s CME audio program consists of four one-hour issues released biweekly in partnership with the Audio-Digest Foundation. The first two hours are now available; the second two hours will be available in June.

Topics and experts include:

**Hour 1**
- The 2010 Revised Classifications of Seizures and Epilepsy
  John J. Millichap, MD
- Status Epilepticus
  Lawrence J. Hirsch, MD, FAAN
- EEG and Epilepsy Monitoring
  Paul Ratecki, MD
- Neuroimaging in Investigation of Patients with Epilepsy
  Fernando Cendes, MD, PhD

**Hour 2**
- Management of Childhood Epilepsy
  Tracy A. Glaser, MD
- Pregnancy, Epilepsy, and Women’s Issues
  Page B. Pennell, MD
- Epilepsy and Neuropsychological Comorbidities
  Leslie A. Rudzinski, MD

**Hour 3**
- Antiepileptic Drug Treatment: New Drugs and New Strategies
  Jacqueline A. French, MD
- Surgical Treatment of Epilepsy
  John W. Miller, MD, PhD
- Neurostimulation for Drug-resistant Epilepsy
  Christopher M. De Giorgio, MD

- Dietary Treatment of Intractable Epilepsy
  Eric H. Kossoff, MD, and Mackenzie C. Cervenka, MD

**Hour 4**
- Non-epileptic Behavioral Disorders: Diagnosis and Treatment
  Selim R. Benbadis, MD
- Practice Issues: Monitoring and Antiepileptic Drug Safety
  L. James Willmore, MD
- Ethical Perspectives: Genetic Testing in Children with Epilepsy
  Courtney J. Washko, MD

Continuum Audio includes probing discussions with authors of selected articles published in the official CME journal of the AAN, Continuum: Lifelong Learning in Neurology®. These conversations focus on actual case studies and emphasize important aspects clinicians face in their day-to-day practices. The topics covered in Continuum Audio mirror the current print issue with new one-hour programs available biweekly. With 24 hours of audio programming per year, participants may earn up to 2 AANA PRA Category Credits® per program (or up to 48 per year).

New Health Policy Fellowship Coming

The AAN is partnering with George Washington University to develop a two-year Neurology Health Policy Research Fellowship that members will be able to apply for in the fall of 2013 and begin in 2014. The selected applicant will be able to obtain a master’s degree in health policy. Tuition and an annual stipend will be provided by the fellowship. Course work would include biostatistics, epidemiology, health policy analysis, health economics, and health policy research design. At the same time, the fellow will gain experience working in a congressional, federal, or executive office, and receive clinical research training while maintaining his or her clinical skills.

For more information, contact Melissa Showers at mshowers@aann.com.
Miyasaki Supports Foundation Through Word and Deed

Janis Miyasaki, MD, MEd, FRCP, FAAN, has long been impressed with the American Brain Foundation’s commitment to helping fellows in research training. “The vision to identify this commitment as key to neurology continuing to progress and remain innovative and address patients suffering is critical. Without the training fellowships, many neurologists would abandon their research aspirations. Research changed neurology from the ‘Diagnose then Adios’ specialty to one with an impressive armamentarium for therapy and better understanding of neurologic illnesses.”

And so began Miyasaki’s seven-plus year support to the American Brain Foundation, making not only financial contributions, but donating countless hours of her time to helping the Foundation achieve its vision to cure brain disease.

A member of both the American Academy of Neurology’s and AAN’s Institute’s Board of Directors and an AAN Education Committee member, Miyasaki also donates her time and energy to numerous American Brain Foundation initiatives throughout the year. Most recently, she served on the physician work group for the Brain Health Fair which took place during the 2013 AAN Annual Meeting in San Diego. The event brought together close to 2,000 San Diego area patients, families, and caregivers for a free, fun, daylong opportunity to learn more about neurologic disease from experts like Miyasaki. “Outreach to the community through efforts like the Brain Health Fair is essential for patients, families, and caregivers for a free, fun, daylong event that helped connect those affected by a neurologic disease with important information and resources to win the battle in the fight for cures.”

The fair began with a keynote speech by American Brain Foundation Chair John C. Mazzotta, MD, PhD, FAAN, who discussed advances in brain imaging research in neurologic disease. Linda M. Selva, MD, FAAN, followed with a report on the efforts of AAN neurologists in meeting the challenges to find tomorrow’s treatments for brain disease.

Engaged visitors were given a unique opportunity to participate in Brain Health classes, physician-led preventative health booths, blood pressure checks, useful dance therapy techniques, “brain power foods” cooking presentation, and live demonstrations of an EEG machine and transcranial Doppler scanner.

Paying it Forward

Brain Health Fair Attracts San Diego Residents

Patients, their families, and caregivers flocked to the American Brain Foundation’s third annual Brain Health Fair on Saturday, March 16, during the 69th AAN Annual Meeting. The event was held in conjunction with Mayor Bob Filner’s proclamation that March 16, 2013, be “Brain Health Awareness Day” in San Diego. Nearly 2,000 people—a new record—participated in the free, daylong event that helped connect those affected by a neurologic disease with important information and resources to win the battle in the fight for cures.

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AAN Applauds Obama Administration’s Brain Research Initiative

Continued from cover

Foundation has been funding the most promising research by the best and brightest neurology researchers in the world. Since 1993, the Foundation has provided more than $18 million dollars in research grants and supported more than 110 researchers. “We welcome the president’s ambitious and critically needed backing of the neuroscience community, and we look forward to learning more about this project and helping the administration in any way we can.”

AAN Executive Director/CEO Catherine M. Rydell, CAE, attended the White House announcement and met with President Obama and other leading participants in the field of brain research as the administration outlined the goals of its plan. Brain disease affects 1 in 6 Americans, or 50 million people in the US. The annual economic impact is $400 billion dollars. The cost of caring for patients with neurologic disease is currently about 300 times the research investment, yet funding for research into cures for brain disease is becoming scarce at a time when tremendous treatments are on the horizon. Funding of the National Institutes of Health is at an all-time low, as federal funding for research through NIH has decreased every year since 2003.

Thank You

The American Academy of Neurology (AAN) and the American Brain Foundation (ABF) would like to thank these supporters who, along with the supporters cited in the March 2013 issue of AANews, helped make the 2013 Annual Meeting in San Diego a tremendous success.

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Annual Meeting Task Force
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Continued on page 26

Oxtellar XR is now available in your area. For more information visit www.OxtellarXR.com

Oxtellar XR is indicated as adjunctive therapy of partial seizures in adults and in children 6 years to 17 years of age.

WARNINGS & PRECAUTIONS

• Clinically significant hyponatremia (sodium <125 mEq/L) may develop during treatment. Measurement and laboratory tests of serum sodium concentrations should be considered for patients during maintenance treatment with Oxtellar XR, particularly if the patient is receiving other medications known to decrease serum sodium levels. Discontinuation of oxcarbazepine treatment may be clinically required.

• Rare cases of anaphylaxis and angioedema involving the skin, mouth, tongue, throat, larynx, glottis, lips, and eyes have been reported in patients after taking the first or subsequent doses of oxcarbazepine. Angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions after treatment with Oxtellar XR, the drug should be discontinued and an alternative treatment started.

• Patients who have had hypersensitivity reactions to carbamazepine should be informed that approximately 25% to 30% of them will experience hypersensitivity reactions with oxcarbazepine. Patients with a history of hypersensitivity reactions to carbamazepine should ordinarily be treated with Oxtellar XR only if the potential benefit justifies the potential risk. Discontinue Oxtellar XR immediately if signs or symptoms of hypersensitivity develop.

• Serious dermatological reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with oxcarbazepine use. Should a patient develop a skin reaction while using Oxtellar XR, consideration should be given to discontinuing its use. (Please see WARNINGS section of complete prescribing information.)

• Anyone considering prescribing Oxtellar XR must balance the risk of suicidal thoughts and behavior with the risk of untreated illness. Epilepsy and many other illnesses for which antiepileptic drugs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during Oxtellar XR treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

• In patients with severe renal impairment, initiate Oxtellar XR at a lower starting dose and increase, if necessary, at a slower than usual rate until the desired clinical response is achieved.

• Concurrent use of Oxtellar XR with hormonal contraceptives and other oral or implant contraceptives may decrease plasma levels and render these contraceptives less effective. Additional non- hormonal forms of contraception are recommended.

ADVERSE REACTIONS

The most commonly observed >5% adverse reactions seen in association with Oxtellar XR™ and more frequent than in placebo-treated patients were (1200 mg and 2400 mg): dizziness (20%, 41%), somnolence (12%, 14%), headache (8%, 10%), rash (6%, 7%), tremor (6%, 1%), vomiting (6%, 15%), diplopia (10%, 13%), and aphasia (3%, 7%), and fatigue (6%, 3%).

Please refer to Full Prescribing Information for Oxtellar XR™. Please see the brief summary for Oxtellar XR on the adjacent pages.

For more information visit www.OxtellarXR.com

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a history of hypersensitivity reactions to carbamazepine should ordinarily be treated with Oxtellar if signs or symptoms of hypersensitivity develop.

Table 1: Target Daily Dose in Pediatric Patients Aged 6 to 17 Years Old

<table>
<thead>
<tr>
<th>Dose</th>
<th>Patients/Events</th>
<th>Oxtellar XR™/Events</th>
<th>Placebo/Events</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>20 mg/kg</td>
<td>1.8</td>
<td>1.3</td>
<td>1.5</td>
<td>1.9</td>
<td>1.6</td>
<td>1.7</td>
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</tbody>
</table>

Table 2: Risk of Antidepressant-Related Adverse Events

<table>
<thead>
<tr>
<th>Antidepressant</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Fluoxetine</td>
<td>1.2</td>
<td>1.3</td>
<td>1.4</td>
<td>1.5</td>
<td>1.6</td>
<td>1.7</td>
</tr>
<tr>
<td>Sertraline</td>
<td>1.1</td>
<td>1.2</td>
<td>1.3</td>
<td>1.4</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Citalopram</td>
<td>1.0</td>
<td>1.1</td>
<td>1.2</td>
<td>1.3</td>
<td>1.4</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Table 3: Adverse Reaction Incidence in a Controlled Clinical Study of Oxtellar XR™ with Concomitant AEDs in Adolescents

<table>
<thead>
<tr>
<th>AED</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 4: Adverse Reaction Incidence in a Controlled Clinical Study of Immediate-Release Oxtellar Resin in Adolescents

<table>
<thead>
<tr>
<th>AED</th>
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<tbody>
<tr>
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<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
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</table>

Table 5: AED Drug Interactions with Oxtellar XR™

<table>
<thead>
<tr>
<th>AED</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
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<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
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</table>

Table 6: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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<td>1%</td>
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</tr>
<tr>
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<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
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</table>

Table 7: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 8: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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<tr>
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<td>1%</td>
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<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
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</table>

Table 9: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
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</table>

Table 10: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
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</table>

Table 11: Oxtellar XR™ and Other Antiepileptic Drugs

<table>
<thead>
<tr>
<th>Antiepileptic Drug</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 12: OXTTELLAR XR (oxcarbazepine) extended-release tablets, for oral use

<table>
<thead>
<tr>
<th>Indication</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
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</table>

Table 13: OXTTELLAR XR (oxcarbazepine) extended-release tablets, for oral use

<table>
<thead>
<tr>
<th>Indication</th>
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<th>Placebo</th>
<th>Placebo</th>
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<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 14: OXTTELLAR XR (oxcarbazepine) extended-release tablets, for oral use

<table>
<thead>
<tr>
<th>Indication</th>
<th>Placebo</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
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</tbody>
</table>

Table 15: OXTTELLAR XR (oxcarbazepine) extended-release tablets, for oral use

<table>
<thead>
<tr>
<th>Indication</th>
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<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
<th>Placebo</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>1</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>1</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>
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