Spotlight On: Aubagio

In September 2012, the FDA approved Aubagio (teriflunomide), a once-a-day tablet for the treatment of adults with relapsing forms of multiple sclerosis (MS). MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. It is among the most common causes of neurological disability in young adults and occurs at least twice as frequently in women as in men. For most people with MS, episodes of worsening function (relapses) are initially followed by recovery periods (remissions). Over time, recovery periods may be incomplete, leading to progressive decline. There is a chronic,
progressive form of MS and this drug is not approved for use in that clinical scenario.

“In a clinical trial, the relapse rate for patients using Aubagio was about 30 percent lower than the rate for those taking a placebo,” said Russell Katz, M.D., director of the Division of Neurology Products in the FDA’s Center for Drug Evaluation and Research. There are concerns that other drugs already available such as Tysabri and Gilenya are more effective than Aubagio.

The drug contains a Boxed Warning to alert prescribers and patients to the risk of liver problems, including death, and a risk of birth defects. Physicians should do blood tests to check liver function before a patient starts taking Aubagio and periodically during treatment. Also included in the Boxed Warning is an alert noting that, based on animal studies, the drug may cause fetal harm. For this reason, Aubagio is labeled as Pregnancy Category X, which means women of childbearing age must have a negative pregnancy test before starting the drug and use effective birth control during treatment. This potentially limits its use in a population who is at higher risk of having MS.

Cost data is unavailable but it is likely that Aubagio will have an average wholesale price similar to Gilenya. AWP for a 30-day supply of Gilenya is approximately $5,300. Tysabri is an intravenous medication so its AWP comparison is not comparable.

**The High Price Of Non-Hodgkin’s Lymphoma: Zevalin Y-90**

There are multiple treatments available for B-cell Non-Hodgkin’s Lymphoma (NHL). They cover many classes of drugs and often their limiting point is the ability to keep patients in remission after treatment. There is a new form of therapy in the arsenal for NHL with radioimmunotherapy (RIT). RIT is a type of anticancer treatment that combines a source of radiation, called a radioisotope, with an antibody in order to destroy cancer cells. The therapy builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope.

Zevalin (ibritumomab tiuxetan) is a form of radioimmunotherapy indicated for treatment of patients with relapsed or refractory, low grade or follicular B-cell non-Hodgkin's lymphoma (NHL) or for patients with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy. "Refractory" refers to a disease that is no longer responding, or never responded, to common treatments. Zevalin is the first radioimmunotherapy treatment to be FDA-approved as part of first-line therapy for follicular NHL.

The drug is a combination of two prescription medications. It is given with two treatments of rituximab (Rituxan) and one treatment of Yttrium-90 (Y-90), Zevalin. Rituximab is used to reduce
the amount of B-cells in the blood and Y-90 ZEVALIN is given to treat non-Hodgkin’s lymphoma (NHL). The dosage schedule is as below:

- Day 1: Administer rituximab 250 mg/m2 IV
- Day 7, 8, or 9: Administer rituximab 250 mg/m2 IV
  > If platelets >150,000: Within 4 hours after rituximab infusion, administer 0.4 mCi/kg (14.8 MBq per kg) Y-90 Zevalin IV.
  > If platelets >100,000 but <149,000 in relapsed or refractory patients: Within 4 hours after rituximab infusion, administer 0.3 mCi/kg (11. MBq per kg) Y-90 Zevalin iV.

The cycle lasts only 9 days and is typically not repeated. Zevalin comes in 3.2 mg per 2 mL, single-use vials. AWP of the Zevalin package is $45,360, making it the most expensive therapy for NHL. Even at a reasonable markup, the drug could cost payors $90-$100k.

Justice Department Investigating ICD Implantation In Medicare Patients

In what experts say is a novel legal tactic to resolve hundreds of ongoing investigations simultaneously, the Justice Department is e-mailing hospitals across the country today with instructions to examine questionable implantable defibrillator surgeries on Medicare patients and estimate potential penalties under the False Claims Act. Hospitals face a wide range of potential damages. At up to $40,000 apiece (ed note: CMS costs are much lower than commercial payors), the implanted devices that regulate irregular heart rhythms are among the most expensive devices healthcare providers can bill Medicare for, and lawyers say hospitals with high volumes of such surgeries have been asked to provide information of hundreds of cases each.

For more than two years, prosecutors with the Justice Department have been using data-mining technology, civil investigative demands and collaborative meetings with experts to investigate the question of whether some Medicare patients received implanted defibrillators outside of strict CMS rules on when such devices can be used. The “resolution model” document, says each questionable ICD case will be evaluated individually. Hospitals are being told to self-audit the cases and estimate damages, with the severity of penalties based on whether the hospital had medical reasons to violate CMS rules; if patient harm resulted; if the hospital had prior knowledge or a statistical pattern of non-guideline implants; and if a hospital compliance program was in place.

“This is a novel approach for a few reasons,” said DLA Piper attorney Frank Sheeder III, who has hospital clients with defibrillator investigations. “First, the DOJ is articulating standards on clinical
and reimbursement issues. And second, they have been working collaboratively with hospitals and their counsels and have expressed an intention to continue to do so in an effort to bring these cases to reasonable resolutions.” The Justice Department e-mail says it will not penalize every device that falls outside the 2005 CMS National Coverage Determination rules for preventive ICD use. The letter also says the damages model does not modify the CMS coverage rules, which have been criticized by physicians for relying on outdated clinical trials that excluded patients who would benefit from preventive implantable defibrillators.

Sheeder said he disagreed with the Justice Department's decision to pursue the investigation under an anti-fraud statute such as the False Claims Act, which allows for collection of up to triple the amount of actual damages, depending on the severity of the infraction. Other attorneys have said the Justice Department doesn't appear to have a solid legal foundation for any potential prosecution at all. In a 2011 report, two lawyers—Drinker Biddle & Reath partner Jesse Witten and Fredrikson & Byron partner David Glaser—wrote that the 2005 CMS rules did not include language explicitly barring the devices outside the coverage rules. “In other words, the NCD describes circumstances in which an ICD implantation is covered, but does not exclude coverage in other circumstances,” they wrote.

By Joe Carlson Reprinted from Modern Healthcare 8/30/12

"The Doctor Is In." AMS Launches New Live Chat, Exclusive Client Forum And Updated Website.

Have a general question? Getting a tough claim and need some quick help? Need to know where to find information about Best Practices or Administrative tasks? Ever wish you had an MD or CEBS at your fingertips? Well, now you do! The Advanced Medical Strategies newly launched web portal now offers access to these valuable resources via Live Chat. To chat with a live MD/Support Person during prime business hours (US- 9AM - 5PM EST) login to the AMS Portal and click the ‘The Dr. Is In’ link in the upper right hand corner of the site. To get started, provide the requested information and you will be connected to a live, knowledgeable and friendly member of our team.
Introducing The new AMS Website and Client Portal.
Advanced Medical Strategies has launched a new redesigned website www.mdstrat.com and Client Portal with updated content, functionality and useful tools. When logged in to the new AMS customer interface, you will be greeted with an instant overview of all claim requests, medical reviews, underwriting, audits, and negotiations, as well as alerts regarding items that will be of particular interest to you. Some new features of the portal are:

- The medical review section enables automated ICD9 code lookups.
- At a glance my home page shows all current activity and status
- History of requests with the ability to search by Patient Name or Case number
- Ability to request an appeal directly online
- Pre-packaged reports showing key information about completed requests
- Online manual and video guides to assist in portal use
- ICD9 look up tool to quickly look up information by number or description
- Exclusive clients-only forum where medical claims professionals can benefit from others’ recent experiences
- See solutions to complex issues as they cross our desk
- "The Dr. Is In" instant online chat to Dr. Borans for those quick questions!

We at Advanced Medical Strategies hope you find the new live chat, website and Client Portal a great tool to use. If you have any questions feel free to contact AMS President Peter Borans directly at pborans@mdstrat.com.

Case Study: Medicare Repricing

Medicare Repricing should only be utilized when a Plan Document specifies that the allowable charge for certain services, such as dialysis or inpatient hospital, is calculated on the basis of a percentage of Medicare rates. While this wording is found in some Plan Documents, not all TPAs have built the necessary databases to calculate the Medicare allowable amount. There also are certain circumstances where a stop loss carrier limits stop loss reimbursement for a domestic facility to some percentage of Medicare allowable. Stop loss carriers rarely have the necessary databases to calculate the Medicare allowable amount.

In a recent AMS submission for dialysis claims, the Plan Document limited reimbursement for dialysis to 135 percent of Medicare allowable. The TPA was using a vendor that charged 25 percent of savings to reprice the claims at Medicare allowable. The services provided by this
vendor included repricing only. There was no medical review of the submitted charges. AMS’ fee for this same service was 12.5 percent of savings, and included a medical review of the submitted charges. AMS not only saved the client on the fee for this service, AMS identified significant charges for unbundled drugs and supplies, saving the client tens of thousands of dollars.

In another instance, an MGU allowed stop loss benefits for a domestic facility (where the facility is also the self-funded employer) at 125 percent of Medicare allowable. The TPA submitted the domestic claims at full billed charges. After calculation of the Medicare allowable amount, the stop loss reimbursement was reduced appropriately by almost $100,000. The AMS fee for this service was 12.5 percent of savings, rather than the 25 percent charged by other vendors. In addition, at the same time, the provider’s bills were reviewed to determine if there were any medical issues that required attention. None were found, and there was no charge for this additional service.

These are but two examples of circumstances where AMS was able to save clients’ money merely by helping them to enforce existing contract wording. AMS’ fee was less than was charged by other vendors, and AMS offered additional medical review services that were not offered by other vendors.