Sustainable Growth Rate Formula Repealed; Physicians React

Lawmakers overwhelmingly approved a bill to repeal and replace the sustainable growth rate (SGR) formula, and the President signed the bill, calling it a “milestone for physicians.” The Senate voted 92 to eight in favor of the bill; the House passed the bill by a vote of 392 to 37.

The law provides a 0.5% annual increase in Medicare reimbursements for the next 5 years, followed by a to-be-determined system designed to reward physicians based on the quality of care provided. In the new system, higher volume of procedures will not necessarily correlate with increased compensation.

The law also establishes a technical advisory committee to review and recommend physician-developed alternative payment models to be implemented after the 5-year period of 0.5% annual increases.

Paul E. Tornambe, MD, FACS, of Retina Consultants San Diego, said in an interview with Retina Today, “I’m pleased the SGR was repealed. It never made any sense, and Congress knew it, but it made them look fiscally responsible.”

Still, Dr. Tornambe remained skeptical that this was the end of any cuts to reimbursement. “The government will find other ways to decrease our payments,” he told Retina Today. “They have already done it over the years.”

He added that he would “like to know more about the ‘strings’ attached to the repeal.”

William L. Rich III, MD, FACS, president-elect of the American Academy of Ophthalmology, said that repeal of the SGR formula was a step in the right direction but noted that more reform was needed.

“Before any reasonable health policy legislation or regulation could be attempted, we had to let the elephant out of the room,” Dr. Rich told Retina Today. “Now starts the real work of addressing failed federal policies that adversely affect physicians outside large integrated groups and academic centers.”

Dr. Rich said that this was just the beginning of a longer conversation about reimbursement. “Current quality reporting requirements are too volatile,” he said.

Noting, for example, that the high cost of anti-VEGF agents distorts the total cost of care for retina specialists, Dr. Rich said, “the value-based modifier is terribly unfair to retinal doctors because of the cost methodology used.”

Dr. Rich noted that ophthalmologists, despite their concentrated specialty, had a hand in crafting the SGR reform.

“Ophthalmology is a small specialty of 3%; retina doctors are a smaller percentage of ophthalmologists,” Dr. Rich told Retina Today. “However, the American Academy of Ophthalmology has one of the five largest physician [political action committees in Washington] and is usually listed in the top 100 or so most effective advocacy groups. Ophthalmology had a seat at the table and is pleased that the SGR ‘fix’ bill was passed.”

IMPACT Study Did Not Meet Primary Endpoint

The phase 2 IMPACT study evaluating OHR-102 (0.2% squalamine lactate ophthalmic solution, Ohr Pharmaceutical) as therapy for treatment of wet age-related macular degeneration (AMD) in combination with ranibizumab (Lucentis, Genentech) did not meet its primary endpoint, according to a company press release.

The primary endpoint of the study was the number of injections required at 9 months.

The 9-month study randomized patients to a...
combination therapy group (OHR-102 twice daily plus ranibizumab as needed) or monotherapy group (placebo eye drops twice daily plus ranibizumab as needed). Those with classic choroidal neovascularization showed a mean visual acuity gain at 9 months of 11 letters in the combination therapy group and 5 letters in the monotherapy group, a clinically meaningful difference of 6 letters. These results, although not the primary endpoint, were encouraging to researchers, and the company plans to begin targeting populations for treatment in future studies.

In the press release, Jason Slakter, MD, the chief medical officer of Ohr, said, “we expect to commence the phase 3 development program with OHR-102 combination therapy in the second half of 2015.”

### Increased Calcium Consumption Linked to Prevalence of AMD

Patients who reported higher than usual supplementary calcium consumption were at a higher risk for developing AMD, according to research published in JAMA Ophthalmology.1 Researchers reviewed data from participants (n = 3191) in the 2007-2008 National Health and Nutrition Examination Survey. All participants were at least 40 years old. They were interviewed regarding use of dietary supplements and antacid consumption during the month prior to the interview and were evaluated for the presence or absence of AMD by fundus photography.

In total, 248 participants (7.8%) were diagnosed with AMD. The mean age of those with AMD was 67.2 years; for those without AMD, it was 55.8 years. Investigators found that those with self-reported consumption of more than 800 mg per day of supplementary calcium had higher odds of an AMD diagnosis compared with those not reporting more than 800 mg per day (odds ratio [OR], 1.85; 95% CI, 1.25-2.75). The association between higher calcium consumption and presence of disease was stronger in older patients (OR, 2.63; 95% CI, 1.52-4.54), leading researchers to speculate that the association may be due to the longer duration of calcium supplementation in older patients.

The investigators wrote that “the findings [suggest] a threshold rather than a dose-response relationship.”

### Statins May Lower Users’ Risk of Developing Uveitis, Study Found

Statins may be protective against the development of uveitis, and antiinflammatory and immunomodulatory mechanisms may help to explain this association, according to a study in the American Journal of Ophthalmology.2

The medical records of all patients (n = 217,061) in the Kaiser Permanente Hawaii health plan between January 1, 2006, and December 31, 2007, were searched electronically for International Classification of Diseases, 9th Revision, diagnosis codes related to uveitis. The investigators performed a chart review to confirm incident uveitis diagnosis during the study period.

Two control groups were each randomly selected at a 5:1 ratio to cases, and controls were assigned an index date to match their respective case diagnosis date. One control group was selected from the general Kaiser Permanente Hawaii population that had at least one health care visit during the study period. Another control group was selected from the population of Kaiser Permanente Hawaii members who had at least one visit to the ophthalmology clinic during the study period. Statin use was defined as filling a prescription for a statin medication in the year prior to the diagnosis or index date based on an electronic search of the Kaiser Permanente Hawaii pharmacy database for generic product identification codes.

When the investigators applied a conditional logistic regression model with the clinical diagnosis of uveitis as the outcome to assess the relationship between statin use and uveitis, they identified 108 incident cases. Of these, 19% of patients with uveitis had used a statin medication in the year prior to diagnosis compared with 30% of patients in the general Kaiser population control group (P = .03) and 38% of patients in the ophthalmology clinic control group (P < .001). Using the general Kaiser population control group and adjusting for age, sex, race, and autoimmune diseases, the odds of a statin user’s developing uveitis were 48% lower than the odds that someone who did not use statins would develop uveitis (OR, 0.52; 95% CI, 0.29-0.94; P = .03). Similarly, the odds of developing uveitis were 33% lower for statin users compared to nonusers (OR, 0.67; 95% CI, 0.38-1.19, P = .17) when adjusting for these factors and using the ophthalmology clinic control group.


### Phase 2 Study of Integrin Peptide Therapy Begins; Patent Issued

Allegro Ophthalmics began enrolling patients in a phase 2 clinical trial evaluating the safety and efficacy of the integrin peptide therapy ALG-1001 (Luminate) in inducing posterior vitreous detachment for patients with nonproliferative diabetic retinopathy (DR). The company also announced that the US Patent and Trademark Office
issued a patent covering the composition of matter of ALG-1001, as well as its methods of use in the treatment of various ophthalmic disorders, neovascular conditions, and tumors. It is Allegro’s first patent in the United States; the company has other patents pending.

The phase 2 study is a randomized, double-masked, placebo-controlled, multicenter, dose-ranging trial to evaluate the safety and efficacy of intravitreal injections of ALG-1001 in patients with nonproliferative DR. Researchers plan to randomize 100 patients to one of three treatment groups (1.0 mg, 2.0 mg, or 3.0 mg) or placebo. Patients will be evaluated every 4 to 12 weeks.

FDA Issues Positive Guidance for NDA Filing for Uveitis Drug

The US Food and Drug Administration (FDA) has responded to questions submitted by Eyegate Pharmaceuticals regarding the company’s anterior uveitis drug EGP-437, according to a press release.

The FDA informed the company that if data from a planned phase 3 trial meet noninferiority criteria, the data could be used alongside data from a previously completed phase 3 trial to support a new drug application (NDA) filing.

The FDA also informed the company that the agency approves of the design of the upcoming trial, which will be a prospective, multicenter, randomized double-masked, parallel-arm, positive control, noninferiority study comparing the drug with the standard of care for noninfectious anterior uveitis. Researchers plan to enroll 250 participants.

Licensing Rights Granted for Microinjector for Gene Therapy

Clearside Biomedical has granted exclusive licensing rights to Spark Therapeutics for its microinjector technology to deliver gene therapies to the back of the eye, according to a press release. The agreement allows the companies to explore the feasibility of using Clearside’s microinjector technology to deliver viral vector to the choroid and the retina through the suprachoroidal space (SCS).

The microinjector delivers therapeutic agents to the retina and choroid through the SCS without substantial diffusion into the vitreous. The microinjector is currently in a pair of phase 2 clinical trials: one for macular edema associated with retinal vein occlusion. In a phase 1/2 trial, subjects with noninfectious uveitis treated with a single injection of triamcinolone acetonide into the SCS showed improvement in BCVA between 1 and 5 lines.

Actavis Completed $70.5 Billion Acquisition of Allergan

Actavis announced that it has completed the acquisition of Allergan in a cash and equity transaction valued at approximately $70.5 billion. The combination creates one of the world’s top 10 pharmaceutical companies by sales revenue, with combined annual pro forma revenues of more than $23 billion anticipated in 2015.

“The combination of Actavis and Allergan creates an exceptional global pharmaceutical company and a leader in a new industry model—Growth Pharma,” Brent Saunders, CEO and president of Actavis, said in a news release. “Anchored by world-renowned brand franchises, a leading global generics business, a premier pharmaceutical development pipeline and an experienced management team committed to maintaining highly efficient operations across the organization, we are creating an unrivaled foundation for long-term growth.”

Actavis expects the transaction to create about $1.8 billion in operating and financial synergies within 1 year of the close. These synergies exclude any additional revenue or manufacturing synergies and are in addition to the $475 million annual savings previously announced by Allergan in connection with Project Endurance. Actavis further expects to generate strong operating cash flow in excess of $8 billion in 2016, which would reportedly enable the company to rapidly de-lever the balance sheet.

The company has more than 20 products in near- or midterm development, including cariprazine, eluxadoline, Esmya, Aczone X, and DARPin treatment for AMD.