Retina specialists performing vitrectomy procedures billed through Medicare will receive reduced reimbursement from the publicly funded health care program starting on January 1, 2015.

The Centers for Medicare and Medicaid Services (CMS) announced its intention to reduce vitrectomy reimbursement in July 2014. The proposed fee schedule has since been finalized, and physicians billing for a number of codes can expect to see a large reduction in reimbursement (Table). Among other codes being cut, reimbursement for injections will also go down in 2015, although not as dramatically as the vitrectomy codes.

In an interview with *Retina Today*, George Williams, MD, explained that the cuts are part of a procedural review, called a screen, performed by CMS to determine reimbursement according to the Resource-Based Relative Value Scale. A survey performed by CMS revealed that the procedural time for vitrectomy procedures had dropped dramatically over recent years, and, as a result, payments were cut.

“The primary driver of valuation for any procedure is the time it takes, so if the time goes down, the payment goes down. That is the fundamental difficulty with the [resource-based relative value scale] system, that the more efficient you become in performing a procedure, the less you will be paid to perform that procedure,” Dr. Williams said. “We saw that happen with cataract surgery over the years, and now, with sutureless approaches for vitrectomy and transconjunctival techniques, it simply takes us less time to perform the operation.”

Voicing a sentiment echoed by several retina specialists with whom *Retina Today* spoke, Paul Tornambe, MD, of Retina Consultants of San Diego, said “These new rates will make it difficult to make a profit once overhead expenses are accounted for. Surgeons may not be able to afford to perform these procedures.”

Further, Dr. Tornambe pointed out, although more experienced surgeons may perform vitrectomy procedures without encountering a complication—and, therefore, in less time—less experienced surgeons are more likely to encounter a complication, which would require longer surgical time.

“Thus CMS and the [Relative Value Update Committee] penalize high quality care—doing the right thing correctly the first time—because it takes less time,” he said.

Dr. Williams conceded that the cuts are “going to affect whoever has a significant surgical volume,” but that, proportionally, vitrectomy reimbursement rates are consistent with other areas of medicine.

“For the times that [vitrectomy] procedures take, these are still relatively highly paid. It’s simply a fact that, as time goes down, payment goes down. But among other nonophthalmologic procedures that take the same amount of time, these are at or above those levels,” Dr. Williams said.

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**DRCR.net Released Protocol T Data**

DRCR.net released preliminary data from its National Institutes of Health-sponsored Protocol T study, which was designed to examine the safety and efficacy of 3 anti-VEGF agents in patients with diabetic macular edema. The data were released to Regeneron and Genentech, both of which also sponsored the trial, during the recent American Academy of Ophthalmology (AAO) Annual Meeting, but the information was not released to the public.

According to press releases from Regeneron and Genentech, the study demonstrated differences in visual acuity gains among patients assigned to 2.0 mg aflibercept (Eylea, Regeneron), 0.5 mg ranibizumab (Lucentis, Genentech), and 1.25 mg bevacizumab (Avastin, Genentech), although the significance of the findings was disputed.

According to a press release from Regeneron, the study demonstrated a statistically significant difference in
change in BCVA from baseline, the primary endpoint of the study, in favor of aflibercept.

Also according to the Regeneron press release, patients in the aflibercept group demonstrated greater improvement in BCVA at 52 weeks compared with patients in the ranibizumab and bevacizumab groups. In response, Genentech said in a press release that the 2-letter difference between patients in the aflibercept and ranibizumab groups was clinically comparable.

The DRCR.net study also examined the safety of the 3 anti-VEGF agents. According to the Regeneron press release, rates of arterial thromboembolic events were highest among subjects in the ranibizumab group (5%), followed by the bevacizumab (4%) and aflibercept (2%) groups. The Regeneron press release also said there were more cardiovascular events in the ranibizumab group compared with the aflibercept or bevacizumab groups.

Responding to the safety data, Genentech stressed that DRCR.net reported on "Any Cardiovascular Event," which it said "contains a broad range of symptoms with unclear relationship to anti-VEGF drug use." Furthermore, Genentech said, a higher event rate of "Any Cardiovascular Event" for ranibizumab did not translate into increased serious adverse events, including hospitalization or death.

DRCR.net investigators continue to analyze the data and will present and publish the data in the coming year, although no specific timeline was announced.

**Actavis to Acquire Allergan**

Actavis will acquire Allergan for a combination of $129.22 in cash and 0.3683 Actavis shares for each share of Allergan common stock, according to an Allergan press release. As of the market close on November 14, the transaction will be worth approximately $66 billion, or $219 per Allergan share.

The acquisition is expected to be finalized in the second quarter of 2015.

See page 10 of this issue for more information.

**FDA Approved Aflibercept for Branch Retinal Vein Occlusion**

The US Food and Drug Administration (FDA) approved aflibercept for treatment of macular edema following branch retinal vein occlusion (BRVO). The regulatory body approved the drug for treatment of macular edema following central retinal vein occlusion (CRVO) in 2012. The recommended dose of aflibercept in patients with macular edema following BRVO or CRVO is 2.0 mg every 4 weeks.

The expanded indication is based on the results of the phase 3 VIBRANT study of 181 patients with macular edema following BRVO. In that study, a significantly greater percentage (53%) of patients randomized to receive aflibercept 2.0 mg monthly showed gains of 15 ETDRS letters, compared with 27% of patients who received macular laser photocoagulation ($P < .01$). Patients treated with aflibercept achieved a 17.0-letter mean improvement over baseline in BCVA, compared with a 6.9-letter mean improvement in the laser photocoagulation group ($P < .01$).

**FDA Accepted Application for Ranibizumab for Diabetic Retinopathy**

The FDA has accepted a supplemental Biologics License Application for ranibizumab for the treatment of diabetic retinopathy (DR). The FDA confirmed action date is February 6, 2015. If the indication for ranibizumab were expanded, it would be the first eye drug available to patients with DR.

Submission of the application was based on the results of the RISE and RIDE trials, a pair of identically designed, parallel, double-masked, sham-controlled trials measuring the percentage of patients with DR or diabetic macular edema gaining at least 15 letters in BCVA at 24 and 36 months.

**FDA Approved Application of Implantable Miniature Telescope; CMS Expanded Reimbursement**

The FDA has approved VisionCare Ophthalmic Technologies’ 180-day supplemental application for the Implantable Miniature Telescope for use in patients with bilateral end-stage age-related macular degeneration (AMD) who are 65 years and older.

The approval lowers the age criteria by 10 years, according to a press release. The FDA’s approval was based on clinical data provided by a pivotal safety and efficacy study and a pair of long-term studies that followed patients for 5 and 8 years.

“We are pleased and excited about this important FDA decision,” said Allen W. Hill, President and Chief Executive Officer, VisionCare Ophthalmic Technologies. “We developed the telescope implant to help older adults who’ve missed seeing moments in their life and lost much of their independence. Now, younger individuals, those age 65 to 74, will also have access to this important therapy for treating end-stage AMD.”

The Implantable Miniature Telescope is the only
Severity of AMD in 1 Eye Predicted Likelihood of AMD in Other Eye, Study Found

Patients are more likely to develop AMD in both eyes if 1 eye already has a severe form of the disease, according to a study published in *JAMA Ophthalmology*.1

Researchers in the Beaver Dam Eye Study, a longitudinal population-based study of age-related diseases, examined patients (n = 4379) every 5 years over a 20-year period. Researchers assessed incidence, progression, and regression of AMD by use of the Wisconsin Age-Related Maculopathy Grading System on retinal photographs. Researchers adjusted for age, sex, and the Y402H polymorphism in the complement factor H gene on chromosome 1q.

Severe AMD in 1 eye was associated with increased incidence of AMD and accelerated progression in its fellow eye (levels 1-2: hazard ratio [HR], 4.90 [95% CI, 4.26-5.63]; levels 2-3: HR, 2.09 [95% CI, 1.42-3.06]; levels 3-4: HR, 2.38 [95% CI, 1.74-3.25]; levels 4-5: HR, 2.46 [95% CI, 1.65-3.66]). For patients with less severe AMD in 1 eye, less progression of the disease was seen in the fellow eye (levels 2-3: HR, 0.42 [95% CI, 0.33-0.55]; levels 3-4: HR, 0.50 [95% CI, 0.34-0.83]).

“We estimate that 51% of participants who develop any AMD always maintain AMD severity states within 1 step of each other between eyes; 90% of participants stay within 2 steps,” the researchers said.

American Academy of Ophthalmology Announced Key Milestones for IRIS Registry

The AAO reported that close to a third of the nation’s eye physicians and surgeons are participating in the Intelligent Research in Sight (IRIS) Registry, the first comprehensive database of eye diseases and conditions in the United States.

The IRIS Registry, a centralized data repository and reporting tool, aggregates patient data from electronic health records to perform statistical analysis. It provides information that enables ophthalmologists to improve patient care, potentially reduces the cost and enhances the speed of some large clinical trials, assists in monitoring resource utilization, and complies with federal incentive programs. Less than 1 year after a limited rollout was announced during the AAO’s 2013 Annual Meeting in New Orleans, the IRIS Registry is reportedly being used by more than 5000 ophthalmologists across the country, with data related to more than 10 million patient visits.

“The IRIS Registry is proving to be a revolutionary tool that Academy member physicians are embracing as a catalyst for improving the quality of care we can provide to our patients,” David W. Parke II, MD, CEO of the AAO, said in a news release. “Ophthalmologists are now able to harness the power of many millions of pieces of clinical information in order to make evidence-based patient care analyses that were not previously possible.”

According to the AAO, the ophthalmology database facilitates clinical benchmarking at the practice, regional, and national levels, enabling physicians to monitor patient care, track interventions, and evaluate outcomes across populations. The registry features subspecialty modules that can help analyze how different preexisting conditions, risk factors, disease severity, and demographics affect outcomes for AMD, cataract surgery, diabetic retinopathy, and retinal surgery.

The IRIS Registry is available exclusively to all US-based AAO members and their practices at no cost.

**Ohr Pharmaceutical Announced Phase 3 Study Design**

Ohr Pharmaceutical announced the design of a pair of identical phase 3 studies assessing the efficacy of OHR-102 (squalamine, Ohr Pharmaceutical) drops for treatment of wet age-related macular degeneration when used in combination with ranibizumab (Lucentis, Genentech). The studies’ primary endpoint will be the proportion of patients achieving visual acuity gains of 3 or more lines at 9 months.

All patients enrolled in the trials will be followed for safety for 2 years. During the first year of the trial, participants will be randomized evenly to receive monthly combination therapy (ranibizumab injections plus OHR-102 drops twice daily) or monotherapy (ranibizumab plus placebo). During the second year of the study, participants will receive combination therapy and monotherapy on an as-needed basis.

An interim analysis of the ongoing phase 2 IMPACT study showed that more than twice the proportion of patients in the combination therapy group achieved at least 3-line gains in visual acuity at 9 months compared with those in the monotherapy group (overall $P = .025$; classic lesions $P = .007$).

**New Single-Use Lenses and Laser Probes Introduced**

Quantel Medical has released new laser probes and single-use lenses. The Vatra Probes, compatible with Quantel Supra and Vtra laser systems, have 2 designs: a flexible tip laser probe and steerable laser probe. The flexible tip laser probe has a flexible needle with a memory shape effect, and is operated with a handle that can turn 360°.

The single-use lenses are packaged in a sterile pouch and discarded after each use, reducing the risk of infection encountered with reusable lenses. The single-use lenses use large, flat mirrors to offer a wide field of view.

**Study of Gevokizumab for Behçet Disease Began Enrollment**

A supplemental clinical study assessing the efficacy and safety of gevokizumab for treatment of Behçet disease uveitis opened enrollment, according to a press release from the Xoma Corporation. The study is designed to supplement data from the phase 3 EYEGUARD-B study.

The study, called EYEGUARD-US, will enroll up to 28 patients on an open-label basis to determine if they respond to gevokizumab therapy. Researchers will randomize patients who responded to gevokizumab on day 28 in a 1:1, double-masked fashion; patients will receive either gevokizumab 60 mg or placebo subcutaneously each month.

Behçet disease is an orphan disease that causes chronic vasculitis and most commonly affects patients 20 to 49 years old. Approximately 5000 to 15,000 patients in the United States have Behçet disease; 60% of those patients have Behçet disease uveitis, 1 of the most severe forms of noninfectious uveitis. Behçet disease uveitis may lead to retinal detachment, vitreous hemorrhage, glaucoma, and blindness if not immediately treated.

**New Widefield OCT Modality, OCT Module, and Image Archive Introduced**

Heidelberg has added a new widefield optical coherence tomography (OCT) modality to its Spectralis line of products.

The new module expands the OCT field of view from 30° to 55°, allowing the device to image the macula, optic nerve head, and periphery in a single examination.

The company also introduced a new OCT module and image archiving system at this year’s AAO Annual Meeting in Chicago.

The OCT2 module, an option for all models of the Spectralis product family, combines a 70 kHz A-scan rate with Heidelberg’s TruTrack high-speed active eye tracking to create images of higher quality than formerly available.

The Heidelberg Eye Explorer Picture Archiving and Communication System, or HEYEX PACS, platform was also launched at the meeting. The image manager, which is compatible with the Heidelberg suite, is scalable to small practices and large multicenter clinics.

**Adjustable and Intuitive Laser Probes Unveiled**

Iridex released a new family of Adjustable And Intuitive Extended Reach (A&I XR) laser probes at the AAO Annual Meeting in Chicago. The A&I XR laser probes use both straight and angled configurations to allow the surgeon to reach all parts of the anatomy.

“Using the A&I XR probe, I was able to reach the full periphery of the eye,” Sam Mansour, MD, said in a press release. “Its narrow cone angle allowed me to treat with lower power and further from the retina than with other laser probes.”