Geographic Atrophy—How to Get Paid for New Treatments

Whenever a new treatment emerges, the path to reimbursement is rarely smooth. For example, even after a drug receives FDA approval, Medicare Administrative Contractors (MACs) and other payers may delay coverage and be slow in publishing their policies for it. The new treatments for geographic atrophy (GA) face all those usual hurdles, plus a few unique bumps in the road.

A New Era for GA Treatment

Earlier this year, Syfovre (pegcetacoplan) was the first FDA-approved drug to treat GA, followed more recently by Izervay (avacincaptad pegol). Both drugs target the complement pathway and must be injected on an ongoing basis.

More GA drugs in the pipeline. Over the next few years, pharmaceutical companies are expected to release more GA drugs, targeting different parts of the complement pathway. Once these are approved, their FDA labels may list different indications and limitations, and each drug may have its own unique route to securing payer coverage. When you submit claims for new GA drugs, you can boost your success rate by following the tips below.

Which HCPCS Code?

The Healthcare Common Procedure Coding System (HCPCS) provides alphanumeric codes that are used to bill for items, supplies, and nonphysician services that aren't covered by the CPT codes. For example, the HCPCS codes for Eylea (aflibercept) and Lucentis (ranibizumab) are J0178 and J2778, respectively.

What if CMS *has not* yet assigned a HCPCS code to a new drug? If a new drug doesn't yet have its own permanent HCPCS code, you could use one of the following not otherwise classified (NOC) codes:

- J3490 *Unclassified drugs*
- J3590 *Unclassified biologics*
- C9399 *Unclassified drugs or biologics*

Each payer may have its preferred NOC code for a particular treatment, and the preferred code may vary depending on the circumstances. For example, the two J-codes above would typically be used for a service that is provided in an office, while C9399 would be used for a facility.

Determine payers' preference and submit clean claims. When using NOC HCPCS codes to bill for a new drug, the first key step is to identify which of the codes the payer would prefer you to use. It also is critical to check that your claim is clean, especially for the new GA treatments, given the problems discussed below.

What if CMS *has* assigned a HCPCS code? Even after a permanent HCPCS code is assigned by CMS, other payers may delay the implementation for a few months. However, once a payer implements a HCPCS code, it will insist that you use that code, when applicable, rather than a NOC code.

HCPCS codes for Syfovre. A permanent HCPCS code was assigned to Syfovre for facility use (C9151) effective July 1, 2023, followed by a code for the office setting (J2781) effective Oct. 1, 2023. For both codes, the dosage unit is 1 mg. Since the recommended dose is 15 mg, you would report 15 units.

CMS form 1500. On CMS form 1500, be careful when filling out items 19 and 24A—or their Electronic Data Interchange (EDI) equivalents. Report the medication name and dosage in item 19 and the national drug code (NDC) in item 24A. (For more specific guidance, go to aao.org/retinapm and click "Coding for Injectable Drugs.")

Which ICD-10 Code?

When you submit CPT code 67028 for performing an intravitreal injection, you also need to submit an ICD-10 code to indicate why the service was medically necessary.

No ICD-10 code for GA. Currently, there is no ICD-10 code that is specific for GA. Instead, use H35.31-, which is the code for nonexudative age-related macular degeneration (AMD), and add a sixth character to indicate which eye(s) underwent treatment, and a seventh character to indicate disease stage. The FDA label may state what stage of GA the drug can be used for.

Don't be surprised by initial denials. Historically, nonexudative AMD was a noncovered diagnosis for intravitreal

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injections. Indeed, submitting that diagnosis when billing for anti-VEGF drugs could have triggered a claims review or audit. When you submit a claim that links ICD-10 code H35.31- to CPT code 67028, you may initially receive denials. This is a typical challenge when the FDA approves a treatment for a previously untreatable disease state, but it is less likely to be an issue once payers update their coverage policies.

Wet and Dry AMD in Same Eye?

Patients with GA could also have exudative AMD in the same eye, which you might be treating with anti-VEGF medications. You may want to treat both conditions on the same day, which would require two separate intravitreal injections and may involve—at least initially—reimbursement problems.

MUE problems. Under the CMS Medically Unlikely Edit (MUE) program, CPT code 67028 has long been assigned a MUE value of 1. This means that CMS believes that, in the vast majority of cases, a patient shouldn't receive more than one intravitreal injection in the same eye on the same date of service. Consequently, only one injection per encounter will be paid.

CMS form 1500. With these combined treatments and different indications, it is critical that you link the ICD-10 codes to the CPT and HCPCS codes appropriately in CMS form 1500's item 24E (or its EDI equivalent):

- Link both the nonexudative and exudative AMD ICD-10 codes to CPT code 67028;
- link only the exudative AMD ICD-10 code to the HCPCS code for the anti-VEGF drug; and
- link only the nonexudative AMD ICD-10 code to the HCPCS code for the GA medication.

Payers Need to Update 28-Day Rule for CPT Code 67028

Intravitreal injections of anti-VEGF drugs have frequency limitations. This is typically every 28 days, which means that if you inject an anti-VEGF drug fewer than 28 days after injecting the same eye, either your claim for the second injection will be denied or, if paid, the payer is likely to try to recoup the money in an audit. Some retina drugs, per the FDA label, may extend this window after a certain number of doses.

Because of what is often called the "28-day rule" for CPT code 67028, a payer may initially reject the claim when an intravitreal injection for GA is performed sooner than 28-days after an intravitreal injection in the same eye. Payers will need to update their policies to account for this alternate class of medications—the complement inhibitors—which is distinct from the anti-VEGF treatments.

Getting Started With the New GA Treatments

The process of implementing a new treatment will be more manageable if you break it down into steps, as described in "How to Add a New Retina Drug to Your Practice—11 Steps to Get You Started" (*EyeNet*, July 2023).

Take a phased approach. Because of the varied payment obstacles described above, it may be best to implement the new treatment in phases, provided that such an approach is medically appropriate for individual patients. You could start with the treatment that involves the most straightforward claim—therapy for GA alone—rather than combined therapy for both GA and exudative AMD. Once payer cov erage has been confirmed for that first scenario, start alternating the two treatments at intervals of at least 28 days. Finally, try submitting a claim for two injections on the same day.

Be ready to appeal a denied claim. Prepare a strategy for prompt and appropriate appeals and educate your staff on those procedures. The first step is to confirm that the drug information was reported appropriately on the claim. Then, if appropriate, submit an appeal letter that explains the medical necessity for the intravitreal injection. As payers publish policies and update their claims processing systems, and as more drugs are introduced, there should be fewer denials.

Keep up with payer policies. The new GA treatments have been met with varied coverage from Medicare, commercial payers, and other payers. Most MACs have responded positively and have paid ophthalmologists' claims. A few national Medicare Advantage and commercial plans—including Humana and United Health Care—have published policies for GA treatment. Although some of these policies were initially flawed or overly stringent, they also were promptly revised. Policies will continue to evolve; policies of different payers will vary; and there is a risk that some payers may introduce prior authorization requirements. Key to minimizing denied claims: diligently and regularly access and review the policies of your payers.

MORE ONLINE. For tips on staying current with your MAC's policies, see this article at aao.org/eyenet.

Introducing a New Drug Into Practice

Before implementing new drugs into your practice, review this checklist:

☐ Review the FDA label.

☐ Identify any published payer policies for the new drug and any unique documentation guidelines or required HCPCS codes.

☐ Report with an NOC HCPCS code until a permanent code is assigned.

☐ Check your CMS-1500 form to ensure that you have entered the required information, including in items 19 and 24A (or their EDI equivalents).

☐ Monitor remittance advice notices to ensure that you are being reimbursed appropriately, and create audit reports to monitor correct coding and payer allowables.

☐ Watch for the drug's permanent HCPCS code, review its descriptor (including its dosage unit), and note the date that it goes into effect.

For a more detailed version of this checklist, see "Retina—Biosimilars, Dual Inhibitors, and Coding for New Drugs" (*EyeNet*, May 2023).