

## Part B Insider (Multispecialty) Coding Alert

### Coverage: Beneficiary Rage Leads to Likely Coverage

Taking the **Centers for Medicare & Medicaid Services** to court proved a worthwhile strategy for beneficiaries struggling with the agency's refusal to cover the treatment they needed.

The plaintiffs in *Jalbert v. Thompson* (CA No. 02-01536) received most of what they asked for, and they trumpeted the victory as a complete one. Thanks to their settlement, an independent panel of the **Medicare Coverage Advisory Committee** will review whether CMS should cover vertepofin, a treatment for age-related macular degeneration, an eye disease.

The original complaint filed by Lois Jalbert and a host of plaintiffs including the **Gray Panthers** and the **American Council for the Blind** had sought a review by the Department Appeals Board. But the plaintiffs will receive a faster hearing in front of the MCAC sub-panel than they would have with the DAB, says plaintiffs attorney **Grant Bagley** with **Arnold & Potter** in Washington.

**Agency for Healthcare Research & Quality** Director **Carolyn Clancy** will choose the panel members on the basis of their experience and training in the issues to be considered. She may choose panel members who aren't on the MCAC, but those outside members won't have a vote. The parties to the lawsuit agreed not to contact Clancy to advocate particular panel members or attempt to influence her decision.

The settlement document instructs the panel to consider anew the questions of whether there's adequate evidence to draw conclusions about risks and benefits of vertepofin therapy for patients with AMD and no classic choroidal neovascularization. The panel will consider evidence provided by the plaintiffs, plus any peer-reviewed studies and recommendations from other expert bodies.

CMS will make a "good-faith effort" to stick to the settlement's timetable, which calls for a meeting of the panel within 120 days of the effective date. And CMS will follow its usual MCAC procedures, which call for it to adopt the panel's recommendation within 60 days or explain a decision to reject it.

Members of the public and other "interested parties" will have sufficient time to provide input to the panel.

The lawsuit also attacked CMS for failing to implement a provision Congress passed in the Benefits Improvement and Protection Act of 2000 that had required CMS to allow appeals of its national coverage decisions.

CMS gave many reasons for failing to implement the BIPA provision, including lack of money and the inexperience of administrative law judges, Bagley says. But CMS reversed itself last August by publishing a proposed rule setting out an appeals process for coverage decisions - the same day it responded to the Jalbert suit. "They said it was coincidence. You can draw your own conclusions," Bagley says. CMS tried to use its new proposed rule to avoid the Jalbert suit's allegations.

The plaintiffs agreed to give up the right to sue CMS alleging a failure to publish a final regulation implementing the BIPA coverage appeals provision. They also agreed not to file suit challenging CMS' national coverage decision on vertepofin prior to Oct. 31, 2003. But the plaintiffs reserved the right to sue CMS over its final BIPA coverage appeals rule once CMS publishes that rule. And if CMS fails to publish a final BIPA rule by Oct. 31, the court will convert the dismissal of the Jalbert suit to a dismissal with prejudice.

"The national coverage process, as it became more prominent over the last five or six years, also consistently brought up the question of what happens to someone who disagrees with it," Bagley says. "CMS' response was always, 'Well, ask us

and we'll take another look at it," meaning the same decision-maker would review an issue a second time.