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Glaukos Takes Another Hit From CMS; Investors Respond Negatively As Stock Falls

by Brian Bossetta

The US Medicare agency's new rule for facility fees brings more bad news for Glaukos; Wells Fargo downgrades company’s stock in response.

After cutting the physician fee for the *Glaukos Corporation* iStent well below what analysts had expected last week, the US Centers for Medicare & Medicaid Services (CMS) delivered another potential blow to the company’s bottom line with release of the agency’s proposed Outpatient Prospective Payment System (OPPS) for 2022, which includes facility fees for hospital outpatient and ambulatory surgical center (ASC) settings.

The *proposed rule*, to be published in the Federal Register on 4 August, cut the facility fee for the iStent in ASC settings by 25%, which was lower than Wells Fargo equity analyst Larry Biegelsen anticipated.

Coming on the heels of the Physician Fee Schedule (PFS) issued on 13 July – in which the Medicare agency proposed combining the codes for cataract surgery and stent placement into a single code, thereby lowering the iStent procedure during cataract surgery roughly 38% – the latest move from the CMS resulted in Wells Fargo downgrading Glaukos stock as its shares fell. (Also see "*Latest Physician Fee Schedule Proposal Could Impact Companies’ Bottom Line*" - Medtech Insight, 16 Jul, 2021.)

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As Biegelsen pointed out, the bulk of iStent procedures, 80%, are performed in ASC settings – with Medicare accounting for nearly 80% of the total of those procedures. What that means, according to Biegelsen's analysis, is that these cuts – the physician fee and the facility fee together – could have a significant negative impact on iStent sales in the US.

"Based on our conversations with physicians we believe the magnitude of the reductions could be greater, especially if the proposed physician and facility fees are finalized when the final rules are issued in November," Biegelsen said in an analyst note.

Wells Fargo is forecasting the decline in the company's iStent sales, in combination with cataract surgery, from 2022 through 2025, with decreases of $58m, $68m, $82m and $97m, respectively.

John Leppard, a health care analyst with Washington Analysis, also predicted in an analyst note more turbulence for Glaukos in the wake of last week's proposals and said the reduction in reimbursements for Glaukos could potentially provide an advantage for the company's competitors.

The CMS also increased the facility fee for the *Inspire Medical Systems Inc.* Medical System's sleep apnea device in the hospital outpatient setting while lowering the fee in ASC settings. The company, Beigelsen said, believes the agency erred in this calculation because it increased the old code for vagal nerve stimulation. In 2022, the sleep apnea system is set to receive its own code. The reason Inspire believes it can convince the CMS to adjust the ASC fee to the same rate as the hospital outpatient setting is because the sleep apnea procedure is more complex than for vagal nerve stimulation.

Leppard said he was also surprised at the ASC rate the agency proposed for the Inspire system, especially because in its physician fee rule last week the agency found the sleep apnea procedure to take longer than the vagus nerve procedure and a longer intra-operative time would be unlikely, in Leppard's view, to translate into a material decline in ASC reimbursement.

"Considering that ASC reimbursement rates are largely based on facility invoice and claims data, we would therefore be on the lookout for Inspire payments to be adjusted upward in the final ASC rule due out this fall, absent new information on sleep apnea implant costs," Leppard said.

While Leppard said he expects the agency to correct the ASC rate it set for Inspire, he was not as optimistic for Glaukos. "We view the room for material upside as more limited in that case following the agency's significant proposed reductions to physician reimbursement last week and the extent of the administrative assumptions CMS seems to have employed," he said.

Biegelsen further noted that the iStent and Inspire sleep apnea system – both of which are moving to new codes in 2022 – qualify as "device-intensive procedures," a designation for procedures that have more than 30% of the hospital-based reimbursement based on the cost of the device itself. In other words, "device intensive" allows for ASC settings to be paid at the hospital-level rate for the aspects of the procedure specific to the device, with the remaining non-device services of the procedure compensated at the lower ASC level.

Therefore, Biegelsen said he expects both Glaukos and Inspire will petition the CMS for higher facility fees.

Wells Fargo's outlook for *Teleflex Inc.* and its UroLift system for treating an enlarged prostrate was brighter, however, despite the agency proposing a 20% reduction for the outpatient procedure in its latest PFS.

In its new rule, the CMS proposed a 2.5% increase in facility payment for UroLift procedures in hospital outpatient settings and a 2.7% increase in ASC settings, which Biegelsen said is consistent with Wells Fargo's expectations and should come as a relief to investors given the reaction after the 20% cut in physician fees.

"UroLift procedures remain profitable in these two settings and are slightly ahead of prior years despite the proposed cut in the physician fee component of the overall payment," Biegelsen said. "This should support continued adoption of the technology, in our view."

The CMS is accepting comments on its OPPS rule through 17 September.