

iRhythm Technologies, Inc. (IRTC)

Continued Pressures on Revenue Model

- CMS provides granular detail on the building blocks for reimbursement calculations. The details provide investors with a roadmap to evaluate the ultimate reimbursement rate for the Zio procedures.
- An analysis of iRhythm's allowance for doubtful accounts implies that the company may be stretching to exceed revenue expectations, and is potentially managing bad debt expense to show operating leverage where there is none.
- Medicare's change in reimbursement guidelines for implantable loop recorders is likely to hurt iRhythm's Zio growth as early as Q1 of 2019.
- We expect BioTelemetry's application for a Category I CPT code for extended Holter monitoring to be submitted for the September, 2019 CPT Editorial Panel meeting

I. CMS provides plenty of detail with which to evaluate the eventual Zio reimbursement rate

Our initial report on iRhythm engendered much fruitful discussion with many analysts on both the sell side and buy side. One area of confusion seemed to be the process by which the AMA and CMS set reimbursement rates for procedures in general, and how that might transpire with the Zio in particular. So we want to flesh out some our analysis here.

CMS publishes its Final Rule every year, along with a set of supporting documentation, which provides detail surrounding the calculations for the Practice Expense components of every single CPT code with a national price. As we discussed in our initial report, the code that supplies almost all of iRhythm’s revenue – 0297T – is a “Practice-Expense-only” code. In other words, there is no Physician Work component to the reimbursement calculation because the “procedure” is not performed in a doctor’s office, but at iRhythm’s IDTF in Houston. Practice Expense reimbursements are much more straightforward than Physician Work reimbursements – CMS simply adds up the following:

- Labor – the number of minutes of staff labor it takes to perform a procedure multiplied by a pre-determined per-minute rate.
- Supplies – any office or medical supplies necessary to perform the procedure.
- Equipment – the cost of the equipment required to perform the procedure.

Given the detail provided by CMS, it’s worth understanding how they get to the Holter and Event Monitor rates, which tells us most of what we need to know for how the Zio reimbursement rate will be determined. The breakout of the various components based on the [CMS 2019 Final Rule Practice Expense Inputs](#) are as follows:

Holter and Event monitor CMS Practice Expense inputs – 2019			
Holter scanning analysis with report		Event Monitor Transmission & Analysis	
<i>CPT Code 93226</i>		<i>CPT Code 93271</i>	
Supplies		Supplies	
10 printed pages	\$ 0.09	Electrodes & Batteries	\$ 12.11
Labor		Labor	
52 Minutes of Technician time		143 Minutes of Technician or RN time	
@ 37c/minute	\$ 19.24	@ 37c/minute	\$ 52.91
Equipment		Equipment	
Holter monitor & Holter analysis system	\$ 15.33	Event monitor & Event monitor transmission & analysis system	\$ 114.37
Total Reimbursement:	\$ 34.66	Total Reimbursement:	\$ 179.39

Source: CMS 2019 Final Rule [supporting documents](#), Kerrisdale analysis

The “supplies” component of the Zio monitoring is likely negligible – batteries, 500MB of flash memory, and the patches. It’s possible that combined those amount to approximately the same as the Event Monitor supplies, which add up to about \$12. In terms of labor, our discussions

with iRhythm competitors that employ former iRhythm technicians indicates that technician time analyzing the Zio patch recording is not very different than the time it takes to analyze a Holter monitor recording. It's certainly less time than the 30-day Event Monitoring procedure given that the latter is performed over 30 days rather than 14, and frequently involves alerting a nurse or doctor in real time to inspect the occurrence of an arrhythmia. Even granting 90 minutes of technician time, at the same hourly rate as Holter and Event monitoring, that would add up to \$33.30.

The Equipment portion of the practice expense inputs are a bit more complex, but still easily calculable. For both Event monitoring and traditional Holter monitoring it's the sum of: (1) the total cost of the monitor, amortized over the expected number of times the monitor will be used and (2) the total cost of the software and hardware used to analyze the ECG recording, also amortized over the expected number of times the system will be used to perform ECG analysis. For iRhythm, that sounds very much like what the company includes in its Cost of Revenue:

*Cost of revenue is expensed as incurred and includes **direct labor, material costs, equipment and infrastructure expenses, amortization of internal-use software, allocated overhead, and shipping and handling.** Direct labor includes payroll and personnel-related costs involved in manufacturing, data analysis, and customer service. **Material costs include both the disposable materials costs of the Zio monitors and amortization of the re-usable printed circuit board assemblies ("PCBAs"). Each Zio monitor includes a PCBA, the cost of which is amortized over the anticipated number of uses of the board.** [emphasis added]*

iRhythm's Cost of Revenue in its 2018 fiscal Q4 was \$10.5 million, and based on their market share estimates, they performed about 150-180 thousand procedures, for a cost-of-revenue per procedure of approximately \$59-70. Even taking the high end of that, we get the following for the Zio reimbursement rate under a Category I code:

Zio monitor Practice Expense estimated inputs	
Zio/Extended Holter scanning analysis with report	
<i>CPT Code 0297T</i>	
Supplies	
Batteries, Flash memory, Patches	\$ 15.00
Labor	
90 Minutes of Technician time	
@ 37c/minute	\$ 33.30
Equipment	
Zio Monitor & Zio Analysis System	\$ 70.00
Total Reimbursement:	\$118.30
<i>Source: Kerrisdale analysis</i>	

The direct costs are then adjusted by CMS for regional variation in prices and other minor adjustment factors (e.g., that's how the \$179 of Event monitoring costs result in a national reimbursement rate of \$170). We'd expect that if the RUC surveys extended Holter monitoring in detail, the reimbursement value that would result from that process would be somewhere around \$120, as per the above. That's remarkably similar to the \$106.48 cost that hospitals report for performing 0297T in the official [statistics](#) from the CMS [Hospital Outpatient Prospective Payment System](#) (i.e., when the procedure is performed by the hospital and its staff rather than by iRhythm's IDTF). More realistically, the RUC will conduct a "crosswalk" comparison to Event Monitoring and simply recommend that CMS reimburse extended Holter monitoring at the same rate.

If there's one takeaway from the reimbursement discussion, we think it's the following: iRhythm's IDTF-centric business model is based on providing a service rather than selling a medical device. The company supplies the devices for free and bills third party payors for a glorified ECG analysis. This model is uniquely suited to succeed as a temporary procedure, reimbursed through ad-hoc negotiations with CMS regional contractors in the absence of any scrutiny of the underlying expense structure. But that same model is also intrinsically destined to fail when the one procedure it relies on is transitioned into a permanent code. That's because, as the AMA states, the official RVU-based reimbursement process is fundamentally built on the principle that payments for services "should vary with the resource costs for providing those services."

II. iRhythm is aggressive in its accounting for bad debt

iRhythm collects revenue from primarily highly credit-worthy customers such as CMS, commercial health insurance providers, the Veterans Administration (VA), and large IDNs. But in the process of performing procedures on large numbers of patients, there are inevitably disputes regarding billable amounts, reimbursable amounts, necessity of the procedure, and other matters. iRhythm accounts for these concessions to third party payors in a way we believe is convoluted and aggressive. It also seems to indicate that the company is stretching in order to beat its own revenue growth targets.

The company keeps two balance sheet accounts for these concessions:

- Allowance for doubtful accounts: this account related primarily to revenue collected from CMS and healthcare institutions such as the VA. As iRhythm describes in its 10-K, for these customers "we have not provided an implicit price concession but, rather, have chosen to accept the risk of default, and adjustments to the transaction price are recorded as bad debt expense."

Strangely, accruals for bad debt expense are booked as SG&A rather than an offset to revenue and receivables. Aside from inflating 2018 revenues by \$5.8 million (a non-negligible 4% of total revenues), this has also had the effect of masking the negative

operating leverage shown by the company in its recently reported fiscal Q4. It also seems incredibly strange that, with a consistent set of customers and only one real product line, the accruals and write-offs of bad debts are so erratic.

iRhythm Bad Debt Expense Summary

(\$ in mm)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Beginning Allowance for Doubtful Accounts	\$ 1.8	\$ 2.2	\$ 2.8	\$ 2.8	\$ 3.6	\$ 5.3	\$ 4.9	\$ 7.0
Writeoffs	0.1	0.2	0.5	1.0	1.7	0.8	(0.0)	2.0
Bad Debt Expense	0.6	0.9	0.4	1.8	3.4	0.4	2.1	(0.1)
Ending Allowance for Doubtful Accounts	\$ 2.2	\$ 2.8	\$ 2.8	\$ 3.6	\$ 5.3	\$ 4.9	\$ 7.0	\$ 4.9
As a % of Annualized Revenue	2.6%	3.0%	2.8%	3.2%	4.3%	3.4%	4.6%	2.8%
SG&A Excluding Bad Debt Expense*	\$ 15.0	\$ 17.5	\$ 17.6	\$ 22.7	\$ 22.6	\$ 29.4	\$ 27.3	\$ 33.3
% of Adjusted Revenue**	72.1%	76.3%	71.6%	85.8%	83.3%	83.9%	75.9%	77.1%
% of Revenue as Reported	72.8%	77.2%	72.1%	86.7%	85.1%	84.1%	77.2%	77.0%

Source: iRhythm 10-Qs and 10-Ks, Kerrisdale analysis

* SG&A also excludes stock-based compensation

** Adjusted Revenue is defined as reported revenue minus the accrual for doubtful accounts

- Contractual allowance: for commercial payors with which iRhythm has contractual arrangements for reimbursement amounts, “we are providing an implicit price concession because, while we have a contract with the underlying payor, we expect to accept a lower amount of consideration when claims are adjudicated...the implicit price concession is recorded as variable consideration to the transaction price and recorded as an adjustment to revenue as a contractual allowance.” This is closer to how bad debt expense is accounted for at companies with similar revenue profiles such as BioTelemetry Inc.

Here too, the pattern of accruals is erratic considering the consistent nature of the customer base and single-product revenue stream. Much more concerning, though, is the recent quarter’s accrual – about 13% of the company’s gross revenues were given up in price concessions to third party commercial payors. We believe that this indicates that either iRhythm is so aggressively pushing utilization of the Zio patch that commercial insurers are beginning to push back on unnecessary procedures, or that the rapid utilization increases have led at least some commercial insurers to demand price concessions from iRhythm even in the face of previously negotiated contracts.

iRhythm Contractual Allowances Summary								
(\$ in mm)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Beginning Contractual Allowance	\$ 2.3	\$ 3.5	\$ 5.0	\$ 5.7	\$ 7.4	\$ 8.5	\$ 7.0	\$ 8.0
Adjustments	0.1	0.0	0.6	(0.0)	0.0	3.1	(0.6)	3.8
Contractual Allowance Accrual	1.2	1.6	1.3	1.7	1.0	1.6	0.4	6.4
Ending Contractual Allowance	\$ 3.5	\$ 5.0	\$ 5.7	\$ 7.4	\$ 8.5	\$ 7.0	\$ 8.0	\$ 10.6
As a % of Annualized Revenue	4.0%	5.3%	5.7%	6.6%	6.9%	4.9%	5.2%	6.1%
Contractual Allowance Accrual as a % of Gross Revenues*	5.3%	6.2%	4.9%	5.7%	3.2%	4.3%	1.0%	12.9%

Source: iRhythm 10-Qs and 10-Ks, Kerrisdale analysis
 * Gross Revenues are defined as revenues plus the contractual allowance accruals

Overall, the details of iRhythm’s accounting for bad debt expense lead us to believe that:

- iRhythm systematically inflates its revenue numbers compared to other medical device companies.
- Given erratic accruals, iRhythm potentially uses “cookie jar” style accounting in accruing for bad debt expense and contractual allowances, resulting in misleading metrics on both the revenue and operating income lines.
- Operating leverage is going in the wrong direction, further illustrating the inherently unprofitable nature of iRhythm’s business model.
- Most importantly, the recent quarter’s contractual allowance accrual seems to indicate that commercial insurers are pushing back on the Zio either through demands for price concessions or reimbursement rejections.

III. The Zio faces near term headwinds from a little-discussed change in CMS rules for implantable cardiac monitors

As we’ve continued our channel checks and due diligence in recent weeks, we found another near-term risk to iRhythm’s revenue growth that we potentially underappreciated previously. Starting on January 1st, 2019, new CPT Codes went into effect for the insertion and removal of implantable loop recorders (ILRs). ILRs are the gold standard of continuous heart rhythm monitoring. They are implanted subcutaneously in a minimally invasive procedure taking about 5 minutes and continuously monitor heart rhythm for as long as they are implanted, generally about 3 years.

For the first time in the history of ILR implantation, the new codes are [eligible for payment](#) “when performed in the non-facility setting.” In other words, cardiologists and EPs can now perform ILR implantation in their office, rather than the hospital. ILRs provide continuous recording, as well as periodic transmission of data to a central station that allows the attending physician to check up on the patient at any time (and bill for it monthly). The most important point to note here is that the reimbursement for ILR implantation allows the physician to be paid thousands of dollars compared to the reimbursement of about \$30 for the application of a Zio patch. The physicians

we spoke with also firmly believed that the reliability, clarity of signal, length of monitoring, and real time capabilities of the ILR make it the preferred solution for long term monitoring, obviating the need for patch monitoring and potentially even Event Monitoring or Mobile Telemetry.

We're not sure whether the financial incentives here have any impact on the physician views of ILR utility, but we believe that the presence of a new high-reimbursement procedure in the office setting that competes with the Zio patch presents a significant risk to near term revenue growth for iRhythm.

IV. A clarification of the timeline of the Category I code transition

The CPT Editorial Panel calendar for 2019-2021 is [published](#) on the AMA's website. To clarify: the CPT Editorial panel meets three times a year to consider revisions to procedural codes. These revisions include applications for new codes, revisions to existing codes, and – as in the case of the extended Holter codes – the transition of Category III codes to Category I status.

The final meeting to determine the 2021 code set will be held in Seattle between September 26-28, 2019, and the deadline for the applications to be considered at that meeting is on June 25th. That's the date by which we expect BioTelemetry Inc. will file to transition the extended Holter codes into Category I codes for the 2021 calendar year. The agenda for that meeting will be published by the AMA on August 26th, and we expect that it will include the consideration of codes 0295T through 0298T and their transition into Category I codes. That will be the first indication of the Zio's changing reimbursement paradigm, though we wouldn't be surprised if Novitas settled the matter earlier at some point in the next few months.

After the September CPT Editorial Panel meeting, the RUC will take up the reimbursement issue in short order and will have recommendations out to the AMA by the middle of December, which will be publicly discussed at the January 2020 RUC meetings in Phoenix. Essentially, we expect the set of catalysts leading to massive reimbursement cuts to become apparent in less than a year.

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