CLOSER LOOK

MEMORANDUM

Medtronic begins MiniMed 670G Customer Training Phase for select Priority Access Program (630G) participants; full Priority Access Program launch in June - March 7, 2017

Executive Highlights

- Medtronic announced on its LOOP blog that it will begin rolling out the MiniMed 670G hybrid closed loop in a "Customer Training Phase" in the next couple of weeks. This comes about a month earlier than we expected (per JPM). From now until June, "a small group" of Priority Access program participants (MiniMed 630G users) at a "select number" of sites will be able to get on the MiniMed 670G. This will allow Medtronic to validate the hybrid closed loop training and onboarding process.
- In June, Medtronic will initiate the full 670G launch, starting with the rest of the Priority Access Program participants (i.e., those on the 630G), and then opening it up to others interested in transitioning. We're not sure exactly when users not in the Priority Access Program will get access to the 670G. Upgrade details are expected this summer.
- Payer feedback on the MiniMed 670G has been "positive" and "favorable" so far, with "good coverage" at launch expected to increase over time. Pricing and business model has not changed from Medtronic's current CGM/pump systems.
- This confirms expectations for a very controlled, deliberate 670G launch and serves as a reminder that launching automated insulin delivery is a very big task - even for a company as experienced as Medtronic.

Medtronic announced on its LOOP blog yesterday that it will begin rolling out the MiniMed 670G hybrid closed loop in a "Customer Training Phase" in the next couple of weeks. This is about a month earlier than expected following CEO Omar Ishrak's JPM presentation, though as we expected, the launch will be highly controlled and deliberate - a good decision, since the company MUST manage expectations and training carefully.

From now until June, "a small group" of Priority Access program participants (MiniMed 630G users) at a "select number" of sites will be able to get on the MiniMed 670G. This will allow Medtronic to validate the hybrid closed loop training and onboarding process, which will include a dedicated "Start Right" concierge team focused on supporting 670G users. Medtronic will contact Customer Training Phase participants in the next couple of weeks to process 670G orders (insurance, prescription), ship the system, and schedule training.

In June, Medtronic will open up the full 670G launch, starting with the rest of the Priority Access Program participants. We're not sure when those not in the Priority Access Program will get access to the 670G, but presumably that will start to happen in the summer. As of JPM, a full US launch was slated for May-October.

It's unclear how large the Customer Training Launch is, though Medtronic's Mike Hill (VP of Global Marketing, Intensive Insulin Management) told us a "relatively small" and "minimum" number will be included to validate training materials and the onboarding process. We would assume <500 people is a reasonable guess, though that is complete speculation.

We're also not sure how many individuals are currently in the 670G Priority Access Program - i.e., those getting on the MiniMed 630G between August 2016-Now. If we assume Medtronic's US base is roughly

500,000 patients (per its 2016 Advocate Forum), and 1%-3% opted into this Program, that translates to 5,000-15,000 people in the Priority Access Program. We have no idea if that is in the ballpark, but it seems a reasonable starting point estimate.

Mr. Hill and the LOOP blog post also shared some broad early thoughts on payer conversations. Payer feedback on the 670G has been "positive" and "favorable" so far, with "good coverage" expected at launch and increasing over time. As expected following September's FDA approval, pricing and the pump/CGM business model are not changing for the 670G. This certainly opens payer conversations on a positive note: the same price as pump+CGM now, but better expected hypoglycemia, A1c, and time-in-range outcomes (per the 670G pivotal trial data and continued access phase data). For context, the retail price of the newly launched MiniMed 630G system varies widely from $6,000-$9,000 (!), but end-user pricing depends on the payer and plan. It will be interesting to see if payers restrict access to certain groups, how onerous documentation is, and what copays/coinsurance look like. We also wonder if more exclusive deals like the one with UnitedHealthcare are in the works. (We'll hear Tandem's 4Q16 call on Wednesday.)

Overall, we're glad to see this important launch proceeding slowly and carefully, since the first commercial hybrid closed loop will set important precedents for the entire field. This rollout also reminds us that getting an automated insulin delivery system approved is only step one; preparing the customer training, manufacturing, and payer discussions takes time, even for an experienced company like Medtronic.

See below for more details and our Q&A with Mr. Hill.

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- **For those not in the Priority Access Program, Medtronic will offer current customers "similar pathway programs" as it has in the past. More clarity is expected in the summer.** We expect this will include some cash upgrade price for in-warranty pumpers to get on the 670G. We might assume the out-of-pocket will be similar to the upgrade price to go from a Revel/530G pump to the 630G, which is $599 or $3,100 out of pocket (depending on whether the old pump was purchased after or before May 1, 2016, including a $400 trade in credit).
- **What will the 670G training look like?** Education will depend on someone's background, but include the standard ump and sensor training, plus some training around the unique aspects of hybrid closed loop ("Auto Mode"). Medtronic plans to use a variety of standard tools, including physician education, slide decks, demo pumps, FAQs, a getting started guide and instructions for use, etc.
    - **Medtronic does have to teach people three levels of automation for the MiniMed 670G:** "Suspend on Low" (i.e., low glucose suspend), "Suspend Before Low" (i.e., predictive low glucose suspend), and Auto Mode (i.e., hybrid closed loop). We like the personalization option, though with more customizability comes more complexity, more settings, and more training. A tough balance to strike and a lot to teach healthcare providers and patients.
- **The MiniMed 670G label is still not posted on the product's FDA page, and the instruction manual is not yet posted on Medtronic's website.** Mr. Hill told us part of the customer training phase will include final validation of the training materials.

Q&A with Medtronic's Mike Hill (VP of Global Marketing, Intensive Insulin Management)

ADAM BROWN: Many are worried about managing expectations with hybrid closed loop. How is Medtronic thinking about this? What have you learned from previous products, particularly the outcry over the MiniMed 530G/Veo?

MIKE: We have definitely learned. We have changed our language to "pursuing a fully automated, closed loop system," and we're calling this a hybrid closed loop.

We've also been using this time period between approval and launch to set expectations. I've been traveling around the US and talking to physicians and the Medtronic team internally - it's been nice to do some level setting and talk about our *path* to closing the loop. What does a hybrid closed loop do and what doesn't it do? We've rolled this messaging out, though of course we can't do a perfect job. We may talk to someone from the media and emphasize this point, but ultimately, they might still say "an artificial pancreas was approved."

ADAM: But it's pretty clear you're not using the term, artificial pancreas, right?

MIKE: Yes, you'll see we've moved away from "artificial pancreas." We talk about our path to a closed-loop system. The MiniMed 670G is hybrid closed loop. Our pipeline is moving to "advanced hybrid closed loop" (i.e., adding automatic correction boluses with the DreaMed algorithm; see ATTD 2017). That will make it even better and more aggressive, and towards the ultimate goal of full closed loop.

One interesting nuance is the FDA's categorization. If you look it up on the FDA's website, the MiniMed 670G is categorized as an "Artificial Pancreas Device System [APDS]." That's in the product code. So when we put out that message of hybrid closed loop, someone might say, "Hey, the FDA is the authority and it's an APDS - which is technically true."

ADAM: How have payer conversations been going?

MIKE: Fortunately, we're having really positive conversations. I personally had some concerns because of the FDA's "artificial pancreas device system [APDS]" label, but we've been pleasantly surprised. We've had pretty positive conversations and feedback and some good coverage decisions. For the full commercial launch, we expect pretty positive coverage and increasingly positive coverage over time.

ADAM: The pricing and business model will be similar to current pump + CGM, correct?

MIKE: There are always caveats, but we're not changing pricing. That's a good first domino for payers covering pumps and CGMs today - sharing no change in pricing leads to favorable conversations. We're not expecting expanded access from the start. The pump is only approved for type 1s 14 years and up. That's where we're looking to be at launch, with increasing coverage over time.

ADAM: What are some of criticisms and questions you receive about the 670G? For instance, the 120 mg/dl target cannot be customized, or it doesn't give automatic correction boluses, etc.

MIKE: In conversations, we talk about how this therapy performs differently from a manual system. Instead of a physician tweaking all these things, the whole point of hybrid closed loop is to give up some of that minute-by-minute decision making and turn some of it over to hybrid closed loop. The pivotal trial shows it can lead to better results. But we do make it clear that you cannot change the target, it does not give boluses, etc., so there is some education to do.

ADAM: Will the Guardian Sensor 3 have 3-4 fingerstick calibrations per day recommended? What will you educate patients to do?

MIKE: The labeled calibration requires a minimum of two fingersticks per day - one at least every 12 hours. That brings an MARD of 10.6%. With 3-4 fingersticks per day, the MARD goes down to 9.6%. People using the system are usually doing 3-4 calibrations. The education is something we'll be validating in this customer training phase.

ADAM: What have you learned from continued access phase users? Have you changed the product at all?

MIKE: We have learned a ton; it's been a rich source of feedback. There haven't been major product changes, since we had already submitted the system to the FDA. We've been getting feedback as we've been building out the training materials and protocols. From a clinical standpoint, you saw some of the data at ATTD [Dr. Satish Garg's presentation covering Barbara Davis Center users], and we've been happy to note all the great

clinical results seem to be durable over the extended time frame. We are more excited and more confident about what this new therapy can do.

ADAM: What has been harder than expected during this preparation phase following September's FDA approval?

MIKE: This has been new for us - taking time between approval and launch. Typically, we get an approval and we're launching immediately, with learning happening on the fly. We're using those past experiences for this launch, and it's been really nice to have this time. With the MiniMed 630G launching, we've also had an overlapping product to learn from.

ADAM: What has been easier than you expected?

MIKE: I think the level and duration of excitement has been unexpected. We were really excited, but we didn't know how much excitement there would be or how long it would last - including from reps, on social media, and beyond. It's been pretty fantastic.

Close Concerns Questions

Q: How many users will be in the 670G customer training phase?

Q: How many users are in the 630G->670G Priority Access Program?

Q: What percentage of current *out of warranty* Medtronic pumpers will get on the MiniMed 670G? What percentage of *in-warranty* Medtronic pumpers will pay the upgrade price to get on the MiniMed 670G?

Q: How will the MiniMed 670G's launch affect other pump companies? Will it steal share or mostly maintain Medtronic's current share? Will the 670G grow the market?

Q: Will the MiniMed 670G and new Guardian Sensor 3 affect Dexcom's growth?

Q: Who is most likely to use the MiniMed 670G at launch? Will MDIs be convinced to switch over and get a pump? Will this product be enough to convince current pumpers to add CGM?

Q: Will real-world outcomes with the MiniMed 670G be similar to the pivotal trial?

--by Adam Brown and Kelly Close