



MEMORANDUM

**FDA approves pediatric indication for Dexcom's G4 Platinum - February 4, 2014**

**Executive Highlights**

- [Dexcom announced](#) FDA approval of a pediatric indication for the G4 Platinum CGM this morning.
- The approval allows Dexcom to market the G4 Platinum to children 2-17 years old in the US (~450,000 patients) and to an additional 800-1,000 pediatric endocrinologists.
- The expanded indication gives Dexcom an advantage over Medtronic, as the MiniMed 530G with Enlite is approved for the narrower group of patients who are 16 years and older.

*This morning, [Dexcom announced](#) FDA approval of a pediatric indication for the G4 Platinum, which allows the company to market its CGM to children 2-17 years old in the US (previously only 18+ years). Some patients this young already had the G4 Platinum, though the need for an off-label prescription limited uptake as prescriptions and reimbursement (in particular the latter) were more challenging to obtain. Indeed, while ~30% of the type 1 population in the US is said to be under 18 years old (~450,000 patients), only 8-10% of Dexcom's installed base is patients younger than 18 years (~4,800-6,000 patients). The approval also enables Dexcom sales reps to call on 800-1,000 pediatric endocrinologists that were previously off limits. In short, this should be a major catalyst for Dexcom's business in 2014 (said CEO Mr. Terry Gregg at [JP Morgan 2014](#), "We've got some upside ..."). The recently expanded sales force (now 90 reps) will be able to call on pediatric endocrinologists immediately.*

*The pediatric and adult versions of the G4 Platinum have identical sensors; the only difference is the addition of two warning screens in the new pediatric version (presumably these would not limit uptake but are just extra safety points). The systems will have a separate SKU for the hardware; it isn't clear if the packaging will look any different. We hope the same packaging could be used (this has been an uncertain question since the 2Q13 call) to limit further additional commercialization costs. No promotions have been announced at this time, though we imagine Dexcom is thinking hard about this, including how it could bundle the G4 Platinum starter kit with the Dexcom Share remote monitoring product (currently under FDA review, with a response expected in 1H14; 2014 launch expected).*

*The pediatric approval also gives Dexcom a major leg-up on Medtronic with children, as the MiniMed 530G with Enlite is only labeled for patients 16 years and older. Currently, Medtronic is continuing to manufacture the Paradigm Revel system with the less accurate Sof-sensor for patients ages 7-15 years. We assume some HCPs will prescribe the MiniMed 530G off label, though as we noted above with Dexcom's G4 Platinum, this barrier certainly limits uptake, both because some HCPs do not want to prescribe off label and because reimbursement with off label products is typically considerably more challenging to obtain. As a reminder, Medtronic will conduct a post-approval study of the MiniMed 530G in pediatrics, which is expected to be similar in study design to the [currently recruiting adult post-approval study](#).*

- **The pediatric approval came about a month later than was optimistically anticipated in the [3Q13 financial results call](#) ("by the end of 2013") - the delay stemmed from labeling discussions with the FDA.** As a reminder, due to differences in the adult and pediatric clinical studies, the FDA required some changes in the label for the pediatric version of the G4 Platinum (e.g., two-year olds were not subjected to the same forced glucose swings as in the adult G4 Platinum study).

- **In our conversation with Dexcom management, the company is most excited that it can now offer the G4 Platinum to patients *as young as two years old*.** We assume Dexcom will exhibit at Friends for Life in Orlando this summer, a great opportunity to reach many more young patients and their caregivers. The opportunity to see pediatric endocrinologists that have been passionate about the product for some time is a very big win - we look forward to watching uptake, particularly after Dexcom's Share is approved.

*--by Adam Brown and Kelly Close*