

FreeStyle Libre obtains national reimbursement in UK for people with type 1 and type 2 diabetes using insulin; major win in tough reimbursement market - September 13, 2017

Abbott [just announced](#) that FreeStyle Libre will be reimbursed across England and Wales, NHS Scotland, and the Health and Social Care in Northern Ireland for people with type 1 and type 2 diabetes using insulin - a tremendous cost-effectiveness victory in one of the toughest reimbursement markets in the world. The policy goes into effect on November 1, though local economy approval through UK Clinical Commission Groups (CCGs) will ultimately determine availability and specific criteria. As we would expect, those desiring reimbursement will now need an HCP prescription for FreeStyle Libre, though presumably the previous direct-to-consumer model (online credit card, no prescription) will still be available too. Abbott confirmed that this decision is separate from [UK NICE's 2015 clinical guidelines](#), which recommended CGM for the first time in certain adults and children with type 1 diabetes - Libre's coverage is much broader than those criteria, as it now includes people with type 2 diabetes on insulin (and there aren't currently caveats for NHS documentation). Abbott has been working with NHS since 2014 to secure FreeStyle Libre coverage, and we'd guess [Diabetes UK's major petition effort](#) helped accelerate this excellent news. The charity [celebrated on twitter](#) today ("We #MadeItHappen"), and this is a great example of grassroots patient advocacy driving real access alongside industry efforts. Of course, Abbott also has REPLACE and IMPACT and real-world data to make its case, along with the cost-effectiveness argument of eliminating fingersticks. Diabetes UK [notes here](#) that the "Fight for Flash" isn't over - local NHS decision makers will ultimately determine criteria in their regions. We hope they get the message! This coverage will really expand access to FreeStyle Libre, as there are an estimated >500,000 insulin users in the UK. Kudos to Abbott for driving so much expanded access so quickly - FreeStyle Libre has partial or full reimbursement in 17 countries now, including wins in Japan ([August](#)) and France ([May](#)) in recent months. The sensor is now available in 41 countries (+1 since August), and the global user base remains at "more than 300,000 people."

- **There are still some coverage questions we're not sure about:** Do patients get a BGM strip allowance on top of FreeStyle Libre, or is it either/or (we hope the former)? What sort of documentation will be needed to obtain reimbursement? How much risk is there that local authorities make coverage criteria difficult?
- **FreeStyle Libre remains under FDA review following submission one year ago in 3Q16.** As of [Abbott's 2Q17 earnings call](#), there were no updates on timing, but the last guidance in [4Q16](#) predicted a fast-approaching 2H17 approval.
 - **The string of national reimbursement decisions presumably bodes well for payer coverage in the US.** US private payers tend to be more generous than national governments, so we expect very strong reimbursement out of the gate for Abbott here in the US, once approved.
- **Dexcom CGM is similarly available in 41 countries**, according to [its global website](#), though we're not sure how many have full/partial reimbursement. As of [1Q17](#), Dexcom continued to work with France and the UK on national reimbursement, with an update expected in the next 6-12 months. The necessary paperwork has been filed, though these processes seem very difficult to predict. Abbott is notably ahead on this front.

| Country/ Region | FreeStyle Libre Reimbursement Details |
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| UK | National NHS reimbursement announced in September, starting on November 1. Regional specifics depend on local economy approval. |
| Japan | Full (National reimbursement) |
| France | Full (National reimbursement) |
| Belgium | Full (national reimbursement) |
| Austria | Full (national reimbursement) |
| Luxembourg | Full (national reimbursement) |
| Switzerland | Full (national reimbursement) |
| Finland | Full (national reimbursement) |
| Sweden | ~100% of all MDIs covered; reimbursed by all regions |
| Germany | >70% of people with diabetes covered by a number of large, public sick funds (health insurance companies) |
| Italy | "Several regions" have agreed to make FreeStyle Libre available to people with diabetes |
| Middle East | A couple countries are covered in the Middle East |
| Chile | Reimbursement available through private plans |
| Denmark | All eligible insulin-using patients have access via municipalities (primary care) or hospitals (secondary care) |
| South Africa | Not specified |

-- by Brian Levine, Adam Brown, and Kelly Close