

NHS ENGLAND – HOW IMPORTANT IS THIS EMERGENT STAKEHOLDER IN UK MARKET ACCESS?

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Introduction

- Since April 2017, NHS England (NHSE) has new powers to negotiate directly with pharmaceutical companies offering innovative high value medicines to the NHS
- These commercial discussions can be triggered if the budget impact for a new technology is expected to exceed £20 million per year in any of the 1st 3 years of use and occur in parallel with the NICE technology assessment
- This research systematically evaluates all innovative therapies reimbursed following commercial discussions with NHSE

Methods

- NHSE press releases were screened, any innovative medicine reimbursement decision identified, and key information extracted
- Analysis dates: 01-April-2017 to 10-Jun-2021

Results

- NHSE have publicly announced successful conclusion of commercial discussions for 20 innovative therapies (4 in 2017, 3 in 2018, 9 in 2019, 2 in 2020 and 2 in 2021), as presented in the table below:
 - 13/20 successful NHSE commercial discussions had NICE positive guidance:
 - 6/13 NHSE press release and NICE Final Appraisal Determination (FAD) were on the same day,
 - 5/13 NHSE press releases preceded the NICE FAD by a mean of 63 days [range: 44-88],
 - Further, conclusion of NHSE commercial discussions were announced before or on the day of regulatory approval for 2/20, notably these represent 2 of the 3 most recent NHSE announcements
 - 2/13 were after NICE FAD.
 - 3/20 had negative NICE appraisals (not recommended or non-submissions)
 - 2/20 [both in 2021] were associated with ongoing NICE assessments
 - 2/20 did not go through NICE (instead were subject to Clinical Commissioning Policies)
 - These 20 include 2 CAR-T cell therapies and 2 gene therapies
- The specific type of commercial agreement is not typically stated but
 - 2 were outcomes-based agreements, 1 was budget-neutral and 1 was a portfolio-wide agreement
- 10 positive HST guidance have been announced since April 2017, 4/10 have had NHSE commercial discussions

Brand name	Generic name	Indication	NHSE press release	NICE guidance published	NICE Outcome	NICE FAD date	NHSE before +ve NICE FAD		Notes
							?	Days	
Kadcyla	Trastuzumab emtansine	3L+ HER2+ mBC	15-Jun-17	19-Jul-17	Recommended	15-Jun-17	same	0	
Strensiq	Asfotase alfa	Hypophosphatasia	05-Jul-17	02-Aug-17	Recommended	05-Jul-17	same	0	HST
Perjeta	Pertuzumab	HER2+ mBC	09-Nov-17	07-Mar-18	Recommended	01-Feb-18	before	-84	post 2013-CDF
Mavenclad	Cladribine	Multiple Sclerosis	09-Nov-17	06-Dec-17	Optimised	05-Nov-17	after	+4	outcomes-based deal
Keytruda	Pembrolizumab	1L PD-L1+ NSCLC	06-Jun-18	18-Jul-18	Optimised (CDF)	06-Jun-18	same	0	CDF review, outcomes-based
Kymriah	Tisagenlecleucel	B-cell ALL	05-Sep-18	21-Dec-18	Recommended (CDF)	16-Nov-18	before	-72	CAR-T
Yescarta	Axicabtagene ciloleucel	B-cell lymphoma	05-Oct-18	23-Jan-19	Recommended (CDF)	07-Dec-18	before	-63	CAR-T
Ocrevus	Ocrelizumab	Multiple Sclerosis	09-May-19	12-Jun-19	Optimised	09-May-19	same	0	2 FADs, one in Sept '18
Spinraza	Nusinersen	Spinal Muscular Atrophy	15-May-19	24-Jul-19	Optimised	03-Jul-19	before	-49	
Emicizumab	Hemlibra	Haemophilia A	21-Aug-19	N/A – Commissioned under an NHSE CCP (Aug 2019)		N/A	N/A	N/A	
Luxturna	Voretigene neparovec	Inherited retinal disease	04-Sep-19	09-Oct-19	Recommended	04-Sep-19	same	0	HST, gene therapy
Brineura	Cerliponase alfa	Batten disease	11-Sep-19	27-Nov-19	Recommended	25-Oct-19	before	-44	HST
Orkambi	Lumacaftor /ivacaftor	Cystic Fibrosis	24-Oct-19	26-Jul-16	Not recommended	N/A	N/A	N/A	Portfolio agreement
Kalydeco	Ivacaftor	Cystic Fibrosis	24-Oct-19	N/A – Commissioned under an NHSE CCP (Mar-2012)		N/A	N/A	N/A	
Symkevi	Ivacaftor and tezacaftor	Cystic Fibrosis	24-Oct-19	09-Aug-18	Non submission	N/A	N/A	N/A	
Epidyolex	Cannabidiol	Dravet syndrome	21-Dec-19	18-Dec-19	Optimised	11-Nov-19	after	+40	
Vitlakvi	Larotrectinib	NTRK+ cancers	21-Apr-20	27-May-20	Recommended (CDF)	21-Apr-20	same	0	
Kaftrio	Ivacaftor/tezacaftor/eleacaftor	Cystic Fibrosis	30-Jun-20	23-Oct-20	Non submission	N/A	N/A	-?	expansion of CF agreement
Zolgensma	Onasemnogene abeparovec	Spinal Muscular Atrophy	08-Mar-21	N/A – NICE appraisal ongoing		04-Jun-21	before	-88	HST, gene therapy
Tagrisso	Osimertinib	1L EGFR+ NSCLC	07-May-21	N/A – NICE appraisal ongoing			before	-?	budget-neutral basis

Conclusions

- NHSE is becoming an increasingly active and important stakeholder in UK market access of innovative therapies and manufacturers should accordingly tailor their early engagement and pricing strategies