prmaconsulting®

pricing, reimbursement
& market access

Implications of a companion diagnostic test for market access of a novel product in GBM

SUMMARY

Through evaluation of 2 scenarios across 5 countries, the client gained an overview of the challenges and risk mitigation options for market access for their product in glioblastoma multiforme (GBM).

CLIENT SITUATION

Testing for MGMT promoter methylation will be required for the administration of a novel product in GBM. The client wanted to understand whether the use of their companion diagnostic test (CDx) could be mandated over existing approaches for methylation testing.

PRMA CONSULTING SOLUTION

Secondary research

The client materials were reviewed and two case studies of analogous CDx-drug pairings identified; this informed development of materials for use in primary research to understand the payer approach, particularly when testing has been available and used in clinical practice before launch of an associated drug.

Primary research

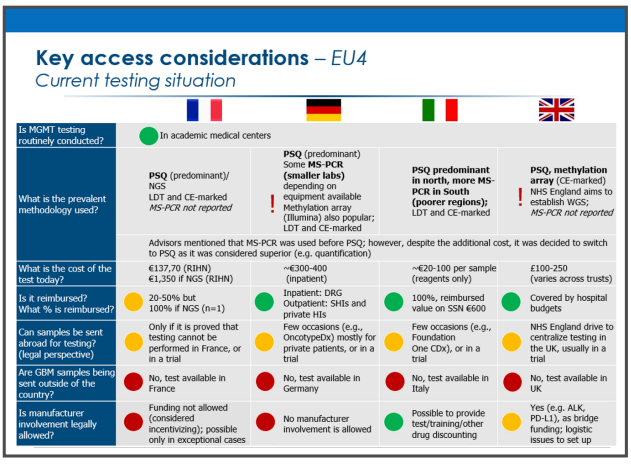
Semi-structured interviews were conducted with a total of 26 advisors (pathologists, national/regional payers, and client Access Leads) across Belgium, France, Germany, Italy, and the UK, to evaluate the adoption and reimbursability of the CDx over existing approaches for methylation testing.

Regulatory label scenario analysis

A slide deck report was developed in which two scenarios were evaluated for the specification of methylation testing in the product's regulatory label for GBM, with recommendations for mitigating the associated challenges and risks in each market.

CLIENT VALUE

- Understanding of differences between countries in the methods, provision, and reimbursement of methylation testing for GBM.
- Insight into the possibility of manufacturer involvement in test funding.
- Evaluation of two scenarios for specification of methylation testing in the product's regulatory label for GBM in the EU, based on detailed feedback from discussions with key external and internal stakeholders.
- Overview of the challenges, risk mitigation options, and implications for market access for the product in GBM in each scenario.



Key access considerations – *EU4*
Current testing situation

Is MGMT testing routinely conducted?	In academic medical centers			
What is the prevalent methodology used?	**PSQ** (predominant)/ NGS LDT and CE-marked *MS-PCR not reported*	**PSQ** (predominant) Some **MS-PCR (smaller labs)** depending on equipment available Methylation array (Illumina) also popular; LDT and CE-marked	**PSQ predominant in north, more MS-PCR in South (poorer regions);** LDT and CE-marked	**PSQ, methylation array** (CE-marked) NHS England aims to establish WGS; *MS-PCR not reported*
	Advisors mentioned that MS-PCR was used before PSQ; however, despite the additional cost, it was decided to switch to PSQ as it was considered superior (e.g. quantification)			
What is the cost of the test today?	€137,70 (RIHN) €1,350 if NGS (RIHN)	~€300-400 (inpatient)	~€20-100 per sample (reagents only)	£100-250 (varies across trusts)
Is it reimbursed? What % is reimbursed?	20-50% but 100% if NGS (n=1)	Inpatient: DRG Outpatient: SHIs and private HIs	100%, reimbursed value on SSN €600	Covered by hospital budgets
Can samples be sent abroad for testing? (legal perspective)	Only if it is proved that testing cannot be performed in France, or in a trial	Few occasions (e.g., OncotypeDx) mostly for private patients, or in a trial	Few occasions (e.g., Foundation One CDx), or in a trial	NHS England drive to centralize testing in the UK, usually in a trial
Are GBM samples being sent outside of the country?	No, test available in France	No, test available in Germany	No, test available in Italy	No, test available in UK
Is manufacturer involvement legally allowed?	Funding not allowed (considered incentivizing); possible only in exceptional cases	No manufacturer involvement is allowed	Possible to provide test/training/other drug discounting	Yes (e.g. ALK, PD-L1), as bridge funding; logistic issues to set up

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+44 (0)1252 786284
info@prmaconsulting.com